IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)
Plaintiff,) C.A. No. 07-729-SLR
v.) JURY TRIAL DEMANDED
GYRUS MEDICAL, INC., GYRUS ENT, L.L.C., and GYRUS ACMI, INC.,) PUBLIC VERSION
Defendants.)

DEFENDANTS' REPLY BRIEF REGARDING MOTION TO DISQUALIFY PLAINTIFF'S COUNSEL WEIL, GOTSHAL & MANGES

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INTRODUCTION

ArthroCare admits crucial facts in its brief and supporting declarations, but glosses over them in an attempt to downplay their significance. The crucial admitted facts include:

- ArthroCare admits that Weil had a legal common interest with Gyrus Group and Gyrus (it is now more than a legal common interest – it is direct representation because Olympus now owns Gyrus Group and Weil continues working on Olympus/Gyrus Group/Gyrus matters).
- ArthroCare admits that Weil received Gyrus Group's and Gyrus's confidential information and attorney work product pursuant to that common interest, in a position of trust.
- ArthroCare admits that the information it received concerns, in part, Gyrus Group's and Gyrus's impressions of their prior patent infringement litigation, the Gyrus/ArthroCare license, and the products accused of infringement in this case.
- ArthroCare admits that Olympus and Gyrus Group, and their counsel, worked closely together to complete Olympus's acquisition of Gyrus Group and were not adverse in those efforts.
- ArthroCare admits that Olympus has not consented to the conflicting representations (in fact, Olympus objects to Weil's representation of ArthroCare).

Those crucial admitted facts, and other undisputed facts, establish that Weil should be disqualified as ArthroCare's counsel in this case. In its attempt to downplay the significance of the above admitted and the other undisputed, highly significant facts, ArthroCare ignores case law which holds that such facts should result in the disqualification of Weil, and mischaracterizes other case law on point. For example, ArthroCare repeatedly asserts that Gyrus must show actual injury (prejudice) to prevail on this motion. To the contrary, the test is not that Gyrus must prove that Gyrus's confidential information was actually conveyed between the Weil teams handling the two conflicting matters to prevail on the motion; rather, the test for Weil's disqualification is whether information Weil gained in one representation is relevant to the other, conflicting representation. That test is met.

II. GYRUS IS NOW PART OF THE OLYMPUS FAMILY, THUS WEIL DOES REPRESENT THE PARENT OF GYRUS

Olympus's acquisition of Gyrus Group is complete. Gyrus Group and Gyrus are now wholly-owned subsidiaries of Olympus. See Exhibit 9¹, which is a February 15, 2008 letter from Olympus to Weil declining Weil's request for Olympus to instruct Gyrus to withdraw the present motion, and stating, ; and Exhibit 10, which is a February 29, 2008 letter from Olympus to Weil objecting to Weil's representation of ArthroCare, and stating that Thus, various statements in ArthroCare's brief such that the motion to disqualify is "particularly inappropriate here where there never was an attorney-client relationship between Weil Gotshal and defendants' parent" (at page 2) are incorrect (and those statements were incorrect when made because Olympus became the parent of Gyrus Group and Gyrus on February 1, 2008).

ArthroCare admits that there is an attorney-client relationship between Weil and Gyrus's parent Olympus. In fact, a declaration submitted with ArthroCare's brief states that there is an ongoing attorney-client relationship between Weil and Olympus on Gyrus Group and Gyrus matters. Hamilton declaration, ¶ 18 ("... Weil Gotshal in fact continues to represent Olympus in relation to certain post-closing matters related to the acquisition"). See also Exhibit 10, referencing Weil's ongoing

Because of that ongoing attorney-client relationship, the argument at pages 12-13 of ArthroCare's brief, that Model Rule of Professional Conduct 1.7(a) does not apply because there is no attorney-client relationship between anyone on the Gyrus side and Weil, is incorrect.

¹ Exhibits 1-8 were submitted with Gyrus's initial brief. Exhibits 9-21 are submitted herewith. The Bobrow, Hamilton and Pearlstein declarations were submitted with ArthroCare's brief.

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The concurrent representations of ArthroCare in this case and Olympus puts Weil in an ethical conflict between clients. For example, Olympus will be kept informed of, have input into, and may even attend ADR proceedings in this case because of its interest in the case. Olympus has begun the process of integrating Gyrus into its United States subsidiary. Weil will thus have clients on both sides of the ADR proceedings and subsequent proceedings, both of whom Weil has counseled as to the subject matter at issue (Gyrus Group's and Gyrus's PK technology and products embodying the technology).

Further, ArthroCare's discovery is broad enough to seek discovery from Olympus, regarding the same subject matter on which Weil represented Olympus. In that regard, in the definitions in ArthroCare's First Set of Requests for the Production of Documents and Things to Gyrus (Exhibit 11, Definition and Instruction 3 on page 2) and ArthroCare's First Set of Interrogatories to Gyrus (Exhibit 12, Definition 3 on page 2), Gyrus is defined as "including without limitation its past and present parents" Olympus is a present parent of Gyrus. The definition proceeds to state that not only is the Olympus parent subject to the discovery, but "other organizational or operating units of any of the foregoing, and all past and present directors, officers, employees, agents and representatives (including attorneys and consultants) of any of the foregoing." The interrogatories and production requests cover information Olympus and Weil received from Gyrus Group during the acquisition. Weil may appear on Gyrus's privilege log. See, for example, Request for Production No. 7 in Exhibit 11, which seeks documents pertaining to almost all aspects of the products in issue. See also Request for Production Nos. 13, 16, 17, 20-23, 26 and 32 in Exhibit 11. While Gyrus will object to such discovery from Olympus, it appears that ArthroCare believes the discovery is proper and will pursue it.

No matter how ArthroCare tries to paint the picture, Weil has a conflict at least because of its present representations of ArthroCare against Gyrus and Olympus on Gyrus matters.

III. ARTHROCARE ADMITS THAT THERE IS AT LEAST A COMMON INTEREST BETWEEN GYRUS, OLYMPUS AND WEIL AND THAT "ATTORNEYS EYES" DATA WAS SHARED IN FURTHERANCE OF THAT COMMON INTEREST

ArthroCare admits that there is at least a common interest between Gyrus Group, Olympus and Weil. See pages 9 and 13 of ArthroCare's brief. Moreover, ArthroCare's declarants admit that to further that common interest, "attorneys eyes" only material was shared between Gyrus Group and Olympus. See, e.g., Pearlstein declaration, ¶ 2.

Although ArthroCare attempts to trivialize that common interest, such common interest is sufficient basis for disqualifying an attorney from representing a third party against a common interest party on overlapping subject matter. See pages 12-14 of Gyrus's initial brief.

ArthroCare's arguments in this regard are an example of ArthroCare's mischaracterization of case law. In the paragraph bridging pages 2 and 3 of its brief, ArthroCare asserts that "[t]his Court rejected exactly this theory ["the common goal of Olympus and Gyrus Group in obtaining regulatory approval and consummating the acquisition" being the basis for disqualifying Weil] in a similar case" (emphasis added), citing Integrated Health Servs. of Cliff Manor, Inc. v. THCI Co., 327 B.R. 200, 206 (Bankr. D. Del. 2005). However, the Integrated Health Servs. case involved only approval regarding licenses. The conflicted counsel did not work towards consummating the matter pursuant to a common interest agreement nor share attorney work product with other counsel. Moreover, the Court explicitly applied the disqualification test of whether "information might have been gained in the first representation" that was relevant to the second representation:

In determining whether a "substantial relationship" exists, "the court need not, nor should it, inquire into whether an attorney actually acquired confidential

information during the prior representation related to the current representation. Rather, the court's primary concern is whether 'confidential information that might have been gained in the first representation [may be] used to the detriment of the former client in the subsequent action." (citing *Commonwealth Ins. Co. v. Graphix Hot Line, Inc.*, 808 F.Supp. 1200, 1204 (E.D. Pa. 1992)). *Id.*

ArthroCare's reliance on *Zirn v. VLI Corp.*, C.A. No. 9488, 1990 Del. Ch. LEXIS 135 (Aug. 13, 1990) and *Jedwab v. MGM Grand Hotels, Inc.*, C.A. No. 8077, 1986 Del. Ch. LEXIS 383 (Mar. 20, 1986), at page 14 of its brief, is also misplaced. In neither case did the merging parties sign and work under a common interest agreement, nor did the parties share work product in order to obtain regulatory approval and to consummate the deal.

Further, in *Zirn* and *Jedwab*, the Courts held that drafts of regulatory submissions were exempt from discovery. *See Zirn* at *5, and *Jedwab* at *3 (finding such drafts to "lie at the heart of the confidential communications that the lawyer-client privilege seeks to protect."). As discussed herein, ArthroCare admits that those communications were shared by Weil and Gyrus Group's counsel pursuant to the Common Interest Agreement. The *Zirn* Court cited Delaware Rule of Evidence 502(b)(3), which states:

Rule 502(b) is a recognition that a disclosure may be regarded as confidential even when made between lawyers representing different clients if in the circumstances, those clients have interests that are so parallel and non-adverse that, at least with respect to the transaction involved, they may be regarded as acting as joint venturers. *Zirn* at *7.

Finally, ArthroCare's attack on the *Nemours Foundation v. Gilbane, Aetna, Fed. Ins. Co*, 632 F. Supp. 418, 424-25 (D. Del. 1986), at page 14 of its brief, is incorrect. ArthroCare wrongly asserts, "[a]s a threshold matter, the court in *Nemours Foundation* denied disqualification, so the case provides little support for Defendants' position." In fact, the *Nemours Foundation* Court disqualified the attorney, but did not disqualify his entire firm because the firm set up an ethical wall at the very outset and precluded fee sharing by the

disqualified attorney. *Id.*, at 424. Neither of those events occurred in this case. The *Nemours* Court applied this standard:

Disqualification of counsel is required "where it appears that the subject matter of a pending suit in which the attorney represents an interest adverse to a prior employer is such that during the course of the former representation the attorney 'might have acquired substantially related material." (citing *American Roller Co. v. Budinger*, 513 F.2d 982, 984 (3d Cir. 1975), which in turn quotes *Richardson v. Hamilton Int'l. Corp.*, 469 F.2d 1382, 1385 (3d Cir. 1972)). *Id.*

IV. GYRUS'S SENSITIVE AND CONFIDENTIAL INFORMATION AND WORK PRODUCT WERE SHARED WITH WEIL TO FURTHER THE COMMON INTEREST, WITH NO WARNING OF THE WEIL CONFLICT

Again, ArthroCare admits the basic relevant facts, but tries to trivialize them. Mr. Shaw, the CFO of Gyrus Group and point person for Gyrus Group on the Olympus acquisition, declares that discussions with Weil and Olympus included Gyrus Group's and Gyrus's confidential information and Gyrus Group's and Gyrus's impressions about Gyrus Group's PK technology and the products embodying that technology, Gyrus's prior patent infringement litigation, and the Gyrus/ArthroCare license. *See* Exhibit 1, ¶¶ 7 and 8. ArthroCare's declarants agree, but try to trivialize those discussions. Hamilton declaration, ¶ 6.

Further, missing is any discussion by Mr. Hamilton (or by any other ArthroCare declarant) of any analysis of the information received from Gyrus Group and Gyrus by Weil.

ArthroCare's brief admits, at page 3, that Weil evaluated the "due diligence information." What was evaluated and analyzed, and how, Gyrus and this Court do not know.

Gyrus Group's and Gyrus's perspective on the PK technology, the use of products embodying that technology (which use allegedly infringes the patent-in-suit), Gyrus's general litigation strategy and settlement of other patent infringement cases, and the Gyrus/ArthroCare license are all highly relevant to this case.

Finally, ArthroCare's declarants admit that Weil and Gyrus Group's counsel shared attorney work product. Pearlstein declaration, ¶ 5.

ArthroCare puts a lot of weight on the assertion that Gyrus's brief and exhibits do not identify "any specific information" that Weil received from its Olympus representation that was conveyed to Weil's ArthroCare team. *See, e.g.*, page 8 of ArthroCare's brief. First, that is irrelevant, as discussed in Section VII below, because the disqualification standard is not that an actual use of specific information must be shown. Second, the assertion is incorrect. *See* Exhibit 1, ¶¶ 7 and 8; Exhibit 2, ¶¶ 5 and 6; Exhibit 3, ¶ 6.

The bottom line is that Weil conducted unfettered interviews of the CFO (Mr. Shaw) and Chief Intellectual Property Officer (Mr. Gadsden) of Gyrus Group to obtain Gyrus Group's and Gyrus's view on the technology in issue in this case, how Gyrus handled past litigations and the Gyrus/ArthroCare license. Those interviews occurred without Messrs. Shaw and Gadsden knowing of Weil's adverse interest. In fact, the complaint was filed the day after one of the interviews. *See* the paragraph bridging pages 3 and 4 of Gyrus's initial brief. As Mr. Shaw declares, he would not have provided Weil any confidential information if he had known that Weil was representing ArthroCare in this lawsuit. Exhibit 1, ¶ 6.

V. OLYMPUS AND GYRUS WERE NOT ADVERSE DURING THE ACQUISITION PROCESS, AND ARE CERTAINLY NOT ADVERSE NOW

ArthroCare's brief ignores the uncontroverted testimony by Gyrus Group personnel, supported by the various Olympus/Gyrus Group agreements, that the Olympus/Gyrus Group acquisition was not an adverse acquisition; rather, it was co-orchestrated by Gyrus Group and Olympus. *See*, *e.g.*, Exhibit 1, ¶ 3, and Exhibit 2, ¶3. That cooperation is admitted by ArthroCare's declarants. *See* Pearlstein declaration, ¶¶ 3-5; Hamilton declaration, ¶¶ 4, 12 and 17.

The paragraph bridging pages 9 and 10 of ArthroCare's brief is particularly deceptive in that regard for this reason. Under British law, when one company procures another, the bid is publicly announced, and thereafter third parties have a set time period to place a higher bid. Exhibit 13. The Olympus/Gyrus Group agreement specifically provided that, because Olympus and Gyrus Group were cooperating in the acquisition, Gyrus Group would not assist or cooperate in any way with a third party doing what the statute provides, i.e., to "overbid" Olympus. See Exhibit 7, ¶ 10. Thus, rather than that clause showing that Olympus and Gyrus Group were adverse, the clause establishes that they were indeed working together toward a common interest.

Further, even under ArthroCare's definition of "adverse" parties, Gyrus is now not adverse to Olympus because Gyrus is a part of the Olympus family.

VI. OLYMPUS HAS NOT CONSENTED

There is a big piece missing from ArthroCare's attempted exculpatory puzzle – Olympus did not consent to Weil's concurrent, conflicting representations. Exhibit 10. ArthroCare's brief tries to dance around Olympus's no consent by asserting that Olympus implicitly consented by continuing to have Weil represent it in the Gyrus Group acquisition after Olympus became aware of the ArthroCare complaint in this case.²

That assertion seriously misstates and misrepresents the facts. As acknowledged by ArthroCare's declarant Hamilton, at ¶ 12, Weil's due diligence, which began in August, 2007, was completed on November 16, 2007 (a Friday), and the acquisition was announced on November 19, 2007 (a Monday). Clearly, on November 15, 2007, Olympus could not replace its acquisition counsel without substantial prejudice. Olympus had no choice but to proceed with Weil. *See also*, Exhibit 1, ¶ 10 (... there was no point in seeking to preclude Weil from having

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² That assertion also ignores the requirement of Model Rule of Professional Conduct 1.7(b)(4) that the consent be "informed consent, confirmed in writing."

access to Gyrus Group's and Gyrus's confidential information after November 14, 2007 because the bulk of such information was conveyed to Olympus and Weil before then."). Olympus did not necessarily "not object" to Weil's continuing representation in the Gyrus Group acquisition at that time - Olympus simply had no choice. Further, as can be determined from Exhibits 9 and 10, Olympus has not given its consent, and declined Weil's request that Olympus

As stated above, even Olympus's alleged, implied "no opposition" is untimely. While ArthroCare's brief focuses on events in mid-November, 2007 and thereafter for the basis of Olympus's implied no objection, the need for Olympus's consent arose months earlier when the conflict between the two representations commenced. Weil began its representation of Olympus regarding the Gyrus Group acquisition on August 6, 2007. ArthroCare's brief, page 5. By then, ArthroCare had already been engaged and was working on the matter that resulted in this lawsuit. Bobrow declaration, ¶ 5.

The present case is readily distinguishable from the implied waiver cases cited by ArthroCare at page 22 of its brief, Elonex I.P. Holdings, Ltd. v. Apple Computer, Inc., 142 F. Supp. 2d 579 (D. Del. 2001) and In re Muma Servs., Inc., 286 B.R. 583, 586 (Bankr. D. Del. 2002). In both those cases, the parties were advised of the conflict at the outset of the conflict, gave verbal consents, and did not initially object in the lawsuits. Olympus/Gyrus Group/Gyrus were not advised of the conflict at the outset, did not give verbal consent, and immediately moved to disqualify Weil.

³ As a side note, the fact that Weil approached Olympus with the request establishes that Weil believes there is a close relationship between Olympus and Gyrus.

Accordingly, ArthroCare's heavy reliance on the implication that Olympus consented to the conflicting representations by continuing to have Weil work on the Gyrus Group acquisition, see, e.g., pages 4 and 16 of ArthroCare's brief, misses the point. Olympus expressly objects to Weil's representation of ArthroCare in this case, as undoubtedly shown by Exhibit 10. Olympus was not given the opportunity to timely object, without suffering substantial prejudice. Olympus should have been given the opportunity to explicitly consent/not consent in August 2007, and not at the eleventh hour of the completion of the Olympus/Gyrus Group acquisition.

VII. ARTHROCARE MISSTATES THE LAW –THE DISQUALIFICATION TEST IS NOT ACTUAL INJURY

One reading ArthroCare's brief is wrongly left with the impression that Gyrus must prove an actual injury to prevail. That is not the test.

Initially, it is inherently impossible for Gyrus to prove actual prejudice, because all of the germane information is within the complete control and knowledge of Weil. Further, discovery of the same is virtually impossible because even ArthroCare's declarants qualify their statements with, "to his/her knowledge." *See, e.g.*, Bobrow declaration, ¶ 8. Moreover, some items, such as Weil's knowledge of Gyrus's mental impressions of litigation, are impossible to discover. That may be one reason why Courts do not require actual prejudice in disqualification cases.

The standard for disqualification is not whether information was actually used by the attorney with the conflict, "rather, it only has to be shown that the conflicting matters are substantially related." Webb v. E.I. DuPont de Nemours & Co., Inc., 811 F. Supp. 158, 161 (D. Del. 1992). Further, as this Court instructed in Conley v. Chaffinch, 431 F. Supp. 2d 494, 498 (D. Del. 2006), a Court should focus on information that might have been acquired by the conflicting representations, and not just the actual information that is received by the conflicting representations. See also page 3 of Gyrus's initial brief.

Therefore, even if ArthroCare's assertion that no relevant information was conveyed between its two teams is correct, the assertion is largely irrelevant. ArthroCare's brief is directed to the wrong standard.

ArthroCare's insistence that this lawsuit has nothing in common, subject matter-wise, to the Olympus acquisition of Gyrus Group is not understood. For example, Olympus procured Gyrus Group because it was very interested in the PK technology and the products embodying that technology. Exhibit 1, ¶ 7. Gyrus Group thus provided information regarding the PK technology and its products embodying that technology to Olympus and Weil and answered questions from Olympus and Weil regarding that technology and those products. Exhibit 1, ¶ 7. It is undisputed that this lawsuit charges that use of products embodying the PK technology infringe the patent-in-suit. *See, e.g.*, Complaint, ¶¶ 8 and 13. *See also* the more detailed discussion on pages 1 and 11 of Gyrus's initial brief. ⁴

Accordingly, it is clear that Weil's conflicting representations meet the Webb and Conley tests.

VIII. NO PROSPECTIVE CONSENT WAS OBTAINED

ArthroCare does not dispute the case law cited at page 17 of Gyrus's initial brief holding that consent in a conflicts situation should be prospective consent. Even the ethics opinion pertaining to parent/subsidiary conflicting representations cited by ArthroCare states that the

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⁴ In all of the parent-subsidiary cases cited on pages 16 and 17 of ArthroCare's brief, the Courts held that a parent-subsidiary relationship could be the basis for disqualification if the matters for the parent and subsidiary were related, but found that the matters before them were not related, unlike in this case. Further, in *O'Neill v. Globe Span, Inc.*, No. 01-2936-LGB, 2001 U.S. LEXIS 23113, at *21 (C.D. Cal. Sept. 19, 2001), the Court found, in part, that the conflicting representations did not overlap time wise, unlike this case.

prospective consent of the affiliated corporation should be obtained. ABA Comm. on Ethics and Prof. Responsibility, Formal Op. 390 at page 14 (1995).⁵

No prospective consent is of record, not even by ArthroCare. The consent by ArthroCare is dated February 18, 2008, months after the conflict arose. Even then, the consent is merely the countersigning of a letter from Weil. As stated above, Olympus objects to the conflicting representations. See Exhibit 10.

Both ArthroCare's and Olympus's consent certainly could have been obtained prospectively as the conflict was uncovered by Weil in its initial conflicts check. Hamilton declaration, ¶ 2. Everything thereafter was completely foreseeable.

Specifically, the fact that Gyrus Group and Gyrus would become part of Olympus was completely foreseeable, as admitted by ArthroCare's declarants. ArthroCare's declarants state that Weil recognized that this was an acquisition at the outset of Weil's representation of Olympus. Hamilton declaration, ¶ 2. Obviously, acquisitions usually end with the acquiring company owning the acquired company. Thus, as of August 2007, when Weil began representing Olympus in the acquisition of Gyrus Group, and at all times thereafter, it was completely foreseeable that Gyrus Group and Gyrus would become part of Olympus.⁶ Yet, Weil

[A]ssuming that obtaining client consent is the preferable course would have several practical benefits. Loyalty is an essential element in a lawyer's representation of any client. Disloyalty is easily perceived by a client, whether or not that perception is well-founded. As this Committee noted in Formal opinion 91-361 (Representation of a Partnership) (1991), if a lawyer explains the implications of a dual representation and obtains the informed consent of both parties, 'the likelihood of perceived ethical impropriety on the part of the lawyer should be significantly reduced.'

⁵ ABA Formal Opinion 95-390 at 14 states:

⁶ In fact, by the day the complaint was filed, November 14, 2007, the fact that Gyrus Group and Gyrus would become part of Olympus was more than "foreseeable," because Weil's due diligence was completed November 16, 2007.

proceeded to represent both Olympus in the acquisition of Gyrus Group and Gyrus and ArthroCare against Gyrus, without advising Olympus (ArthroCare's brief acknowledges, at page 7, that Olympus was not advised of the conflicting representations until after the complaint was filed). Also, according to ArthroCare's declarants, it was well known that, to complete such acquisitions, it was common for the parties to enter into a Common Interest Agreement. Pearlstein declaration, ¶ 4. Thus, in August 2007, not only was it foreseeable that Gyrus and Olympus would become one, it was foreseeable that Weil would enter into a Common Interest Agreement with Gyrus Group and Gyrus to complete the acquisition.

WEIL'S ETHICAL WALL WAS TOO LATE AND IS INEFFECTUAL IX.

As stated at pages 13 and 14 of Gyrus's brief, an ethical wall must be instituted at the outset of a case to be effective. The ethical wall in this case, to the extent it was established, was not established until the end of November, 2007, months after the conflict arose.

Further, the wall, as described in ArthroCare's brief, is inadequate. There is no showing that the documents for the Olympus/Gyrus Group acquisition are kept in a secured location with limited access. Additionally, Weil does not show how the ethical wall is going to be continued forward in time. In that regard, it is well known that large law firms, such as the 1200 lawyer Weil firm, have a lot of turnover. The case schedule provides for this case to pend for at least two years in this Court alone. There is no showing by Weil how the ethical wall is going to be maintained for the two years plus. A single November 2007 memorandum does not do the trick. Weil does not show how the wall will be conveyed to new attorneys and staff.

ArthroCare's case of INA Underwriters Ins. Co. v. Rubin, 635 F. Supp. 1 (E.D. Pa. 1983) is readily distinguishable. In *INA Underwriters*, the wall covered only one attorney – in this case it must cover approximately forty (40) Weil timekeepers. In addition, the Court ordered that all of the conflicting documents in the "walled" attorney's possession be destroyed.

Moreover, the wall must provide that those on opposite sides of the "wall" do not share fees from the matter on the opposite side of the wall. *Nemours Foundation*, 632 F. Supp. at 427. ArthroCare's brief admits that Weil's "wall" does not extend to fee sharing, but apparently takes the position that it does not have to comply with that requirement because its "annual revenues are sufficiently large" such that any fees received from the Olympus representation and this case are "de minimis." ArthroCare's brief, fn. 7 on page 16. That is quite a statement for a firm even as large as Weil to make, as recent surveys establish that attorney fees in cases such as this case are usually in the millions of dollars. Moreover, the list of Weil "timekeepers" who were working on the Olympus acquisition identifies thirty-four (34) timekeepers. See Exhibit B to the Bobrow declaration. Clearly, those fees could be in the millions of dollars.

X. ARTHROCARE MISCONSTRUES THE COMMON INTEREST AGREEMENT PROHIBITIONS

First, ArthroCare's brief, at page 2, incompletely quotes, and thus misquotes, paragraph 7 of the Common Interest Agreement. Paragraph 7 states, "[t]he exchange of data under this Common Interest Agreement shall under no circumstances create a duty from or relationship between any counsel and anyone other than the client of that counsel." ArthroCare omits the underlined limitation on the scope of the paragraph. *See also* ArthroCare's brief at page 9 in that regard.

Second, at page 13 of its brief, ArthroCare mischaracterizes another Common Interest Agreement prohibition. That prohibition, in paragraph 8 of the Agreement, is that none of the parties will "claim that any counsel is disqualified in <u>such litigation</u> by reason of the joint defense effort," with <u>such litigation</u> being any litigation deriving from the Olympus/Gyrus acquisition between the signatories. It does not preclude a claim of conflict of interest as to other

matters. This patent infringement case does not derive from the Olympus/Gyrus acquisition.

ArthroCare is not a signatory. Thus, the conditions for that prohibition are not met.

Further, ArthroCare admits, in the paragraph bridging pages 9 and 10 of its brief, that the Common Interest Agreement bound Weil to conduct "all reasonable endeavors" to effectuate the acquisition. Filing the complaint on behalf of ArthroCare against Gyrus directly conflicts with that contractual duty, as the ArthroCare lawsuit caused Olympus to reevaluate, at the eleventh hour, whether it still wanted to acquire Gyrus Group and Gyrus.

XI. ARTHROCARE HAS NOT REBUTTED THAT WEIL HAD A DUTY OF TRUST TO GYRUS

ArthroCare has not rebutted that Weil had a duty because it received Gyrus Group's and Gyrus's confidential information and work product in a position of trust. ArthroCare's whole argument in that regard, at pages 19-21 of its brief, depends on the incorrect assertion that Olympus and Gyrus were adverse parties. However, even if Olympus and Gyrus were adverse, which they were not, nothing in the Model Rule and the cases distinguish whether the subject information was received in an adverse or non-adverse relationship. For example, the information could have been received in an adverse situation such as a lawsuit, wherein the lawyer receives the adverse party's confidential information pursuant to a protective order. A duty of trust is still created, even in that adverse situation.

XII. GYRUS ACTED TIMELY

ArthroCare presents a smoke and mirror show when it argues that Gyrus did not timely file the disqualification motion. Gyrus's counsel wrote to ArthroCare's counsel on December 20, 2007 raising the conflict and disqualification issue. Exhibit 14. Gyrus's counsel requested that ArthroCare respond by December 31, 2007. ArthroCare wrote on December 31, 2007 stating that it could not respond until the new year. Exhibit 15. When Gyrus did not yet hear anything

from ArthroCare in early January 2008, Gyrus's counsel again wrote to ArthroCare's counsel. Exhibit 16. Only then did ArthroCare's counsel respond (on January 11, 2008), and then via a letter not even on Weil's letterhead. Exhibit 17. It is Gyrus who has acted promptly, while ArthroCare delayed resolution of the issue.

XIII. THE PREJUDICE TO ARTHROCARE IS MINIMAL

This case is just beginning. There is a plethora of qualified patent litigation counsel who could step into Weil's shoes at this early juncture of the case. ArthroCare is not a small family business. Rather, it is a multinational company having sales last year of 223.1 million dollars through September 30, 2007, with sufficient resources to retain new counsel. Exhibit 18.

Further, the claims of the 882 patent were substantially changed during the reexamination proceeding, which occurred after the last litigation involving the 882 patent. See the 882 patent reexamination certificate, Exhibit 19. Specifically, claims 1, 14, 17-20, 23, 24 and 26 were canceled; claims 28, 37, 41, 45-52 and 54-56 were amended; and claims 57-67 were added. The reexamination also resulted in extensive disclaimers that will greatly affect the construction of the surviving claims. For example, during the reexamination, ArthroCare admitted that the 882 patent claims, which are method of use claims, do not encompass use of electrosurgical devices in surgical environments where the tissue is not covered by saline and where the fluid inside the tissue is vaporized. See April 18, 2005 Reply to Non-Final Office Action (Exhibit 20), page 19, lines 14-15; page 20, line 14 - page 21, line 7; page 22, lines 24-28; and page 23, lines 7-17. This is relevant because the present litigation involves Gyrus's "dry field" devices, which are used in surgical environments where the tissue is dry (i.e., not covered by saline and where the

fluid inside the tissue is vaporized instead of vaporizing the saline).⁷ As stated, Weil was <u>not</u> involved in the reexamination.

Further, it is Gyrus's understanding that the 882 patent claims in issue in this case have not been the subject of prior litigation.

First, in the Ethicon case, the 882 patent independent claims at issue were withdrawn by ArthroCare from the case in response to Ethicon's motion for partial summary judgment as to the invalidity of those claims. *See* fn. 1 on page 1 of Exhibit 21.

Second, *ArthroCare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp.2d 638 (D. Del. 2004) case involved many patents. The 882 patent was one of those many patents. Only a few of the <u>dependent</u> claims of the 882 patent were litigated. The independent claims, the primary claims expected to be at issue in this case, were not litigated.⁸

ArthroCare's local counsel, Morris Nichols, was heavily involved in the *Smith & Nephew* case, including interrogating various witnesses during the trial. Moreover, Morris Nichols has significant first chair patent trial experience. Finally, in the early stage of this case, including during the Fed. R. Civ. P. 26(f) conference, ArthroCare's local counsel, Morris Nichols, has played a significant role. Thus, any prejudice to ArthroCare by Weil's disqualification is tempered by the continued involvement of ArthroCare's local counsel, Morris Nichols.

XIV. CONCLUSION

Weil should be disqualified under Model Rule 1.7 for the above reasons and the reasons in Gyrus's initial brief. To summarize, Weil's representation of ArthroCare in this case is

⁷ This is in contrast to all of the prior litigations involving the 882 patent wherein the accused devices were for use in "wet" or flooded surgical environments.

⁸ During the Fed. R. Civ. P. 26(f) conference, ArthroCare was unable to identify the 882 claims that Gyrus allegedly infringes, in violation of that Rule.

"directly adverse" to its client Olympus, and is adverse to its legal common interest with Gyrus Group and Gyrus. Olympus objects to Weil's representation of ArthroCare.

ArthroCare states in its brief that its lawyers should be trusted to not improperly use the information Weil gained (and is apparently still gaining) from its representation of Olympus in the Gyrus acquisition. First, lawyers' integrity alone is not a sufficient safeguard. *Pennwalt Corp. v. Plough, Inc.*, 85 F.R.D. 264, 270 (D. Del. 1980). Further, the integrity of the individual Weil lawyers is not the issue. Rather, it is the institution of Weil and its conflicting representations that are at issue. Weil's own declarations establish that its left hand does not know what its right hand is doing. See Bobrow declaration, ¶ 6, as to the complete lack of knowledge of Weil's Olympus representation, and Hamilton declaration, ¶ 7, disclaiming any knowledge of the lawsuit. In fact, it took Gyrus's counsel to tell Weil's right hand what its left hand was doing. Hamilton declaration, ¶ 7.

Further, this motion was not filed for a tactical advantage. As stated, the case is just beginning. There is a plethora of competent patent litigation counsel that can step in and adequately and sufficiently handle the case on behalf of ArthroCare. The motion was filed because Gyrus and Olympus strongly believe that Weil should not be permitted to represent ArthroCare in this case. *See, e.g.*, Exhibit 1, ¶ 9; Exhibit 10.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

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Thomas J. Pardini
Daniel A. Tanner III
Daniel M. Schneider
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Dated: February 29, 2008 Public Version Dated: March 3, 2008 852397 / 32487 By: <u>/s/ David E. Moore</u>

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Attorneys for Defendants Gyrus Medical, Inc., Gyrus ENT., L.L.C., and Gyrus ACMI, Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on March 3, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on March 3, 2008, the attached document was Electronically Mailed to the following person(s):

Jack B. Blumenfeld Karen Jacobs Louden Morris Nichols Arsht & Tunnell LLP 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899 JBlumenfeld@MNAT.com klouden@mnat.com

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Nicholas Groombridge Weil, Gotshal & Manges LLP 767 Fifth Avenue New York, NY 10153 nicholas.groombridge@weil.com Cabrach J. Connor Kevin Kudlac Weil, Gotshal & Manges LLP 8911 Capital of Texas Highway, Suite 1350 Austin, TX 78759 cabrach.connor@weil.com kevin.kudlac@weil.com

/s/ David E. Moore

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EXHIBIT 9

CLYMPUS CORPORUTION

ślandyrartera Słaniaco Monodith, 3-1 Mata Sminjuku 2-chome, Shinjuku ku, Tokyo 163-0914, Japan

Technology Research Institutes 2951 fahlkawa-cho, Nachlah-shi, Tokyō 192-8507, Japan 2-3 Kuboyana-cho, Hachloli-shi, Tokyo 192-8512, Japan



February 15, 2008

Ian Hamilton, Esq. Weil, Gotshal & Manges One South Place London, EC2M 2WG

Re: Gyrus/Arthrocare Litigation

Dear Mr. Hamilton,

REDACTED

Sincerely,

Olympus Corporation

Hisashi Mori

Director, Member of the Board

H. Mori

Executive Officer

Corporate Planning Division

EXHIBIT 10

Filed 03/03/2008

COMPLECTOR CORPORATION

Hagidi muriyen Tiliddici Manodin, A-Thirid Bidinjuku Antonia, Cirlajuku-ku, Takyo 183-0514, Japan

Technology Research Institutes 2951 istilkawa-cho, Hachloji-shi, Tokyo 192-8507, Japan 2-6 Milogasha-sho, Hachloji-shi, Tokyo 192-8512, Zibin



February 29, 2008

Ian Hamilton, Esq. Weil Gotshal & Manges One South Place London, EC2M 2WG

Re: Gyras / ArthroCare Litigation

Dear Mr. Hamilton,

REDACTED

Sincerely,

Olympus Corporation

He. Mon

Hismshi Mori

Director, Member of the Board

Executive Officer

Corporate Planning Division

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

C.A. No. 07-729 (SLR)

GYRUS MEDICAL, INC., GYRUS ENT, L.L.C., and GYRUS ACMI, INC.,

Defendants.

ARTHROCARE'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS TO GYRUS

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Plaintiff ArthroCare Corporation requests that Defendants Gyrus Medical, Inc., Gyrus ENT, L.L.C., and Gyrus ACMI, Inc. (collectively "Gyrus") produce for inspection and copying the Documents, Electronically Stored Information, and Things requested below at the offices of MORRIS, NICHOLS, ARSHT & TUNNELL LLP, 1201 North Market Street, P.O. Box 1347, Wilmington, DE 19899, or some other agreed upon location, within thirty (30) days from the date of service hereof.

DEFINITIONS AND INSTRUCTIONS

- 1. "Gyrus Products" means each version or revision of the jPlasmaKnife, Dissector PlasmaKnife, PlasmaCision Plasma Trissector, Plasma J-Hook, PlasmaSpatula, and PlasmaCision L-Hook Probe, any predecessor products, prototypes, retrofits, upgrades or new versions of the foregoing, any product previously named any of the foregoing, and each of their respective systems, equipment, parts, and components.
- 2. "ArthroCare" means plaintiff ArthroCare Corporation, its predecessors and successors, past and present parents, subsidiaries, divisions, affiliates, and other organizational or operating units of any of the foregoing, and all past and present directors,

EXHIBIT 11

officers, employees, agents and representatives (including, attorneys and consultants) of any of the foregoing.

- "Defendants," "Gyrus," "You," and "Your" means Defendants Gyrus 3. Medical, Inc., Gyrus ENT, L.L.C., and/or Gyrus ACMI, Inc., and predecessors and successors, including without limitation its past and present parents, subsidiaries, divisions, affiliates, distributors, and other organizational or operating units of any of the foregoing, and all past and present directors, officers, employees, agents and representatives (including attorneys and consultants) of any of the foregoing.
- "Document" shall be interpreted to the full extent permitted by the Federal 4. Rules of Civil Procedure and includes, but is not limited to, e-mail, attachments, files stored on any electronic media, copies of letters, notes and records of telephone conversations, sound recordings, intra-corporate communications, minutes, bulletins, specifications, instructions, advertisements, literature, patents, patent applications, specification sheets and diagrams, work assignments, reports, memoranda, memoranda of conversations, notes, notebooks, drafts, data sheets, work sheets, contracts and agreements, memoranda of agreements, assignments, licenses, sublicenses, opinions and reports of experts and consultants, books of account, orders, invoices, statements, bills, checks and vouchers, brochures, photographs, drawings, charts, catalogs, pamphlets, magazines, copies of magazines, decals, world-wide web and/or internet postings, trade letters, notices and announcements, and press releases, and all other printed, written, recorded, taped, electronic, graphic, computerized printout or other tangible materials of whatever kind known to, or in the possession, custody, or control of Gyrus. A draft or nonidentical copy is a separate document within the meaning of this term.

- 5. "Electronically Stored Information" or "ESI" shall mean, consistent with the comprehensive meaning in Federal Rule of Civil Procedure 34, any writing, drawing, graph, chart, photograph, sound recording, image and other data or data compilations stored in any electronic media from which information can be obtained or translated into a reasonably usable form, other than a Document.
- 6. "Thing" shall mean, consistent with the comprehensive meaning in Federal Rule of Civil Procedure 34, any physical specimen or tangible item, other than a Document.
- 7. "Communication" means any form of oral or written interchange, whether in person, by telephone, by facsimile, by telex, by electronic mail (or email), or by any other medium.
- 8. "Opinion Of Counsel" means any opinions, searches, investigations, reviews, tests, or analyses, whether oral or in writing, that Relate To the scope, novelty, patentability, state of the art, validity, enforceability and/or infringement of the Patent-In-Suit or any related patents or foreign counterparts.
 - 9. "Patent-In-Suit" or "882 Patent" means U.S. Patent No. 5,697,882.
- 10. "Concerning," "Relates To," "Relating To," "In Relation To," and "Related To," mean, without limitation, in whole or in part assessing, reporting, disclosing, constituting, comprising, consisting of, containing, concerning, regarding, embodying, reflecting, describing, discussing, analyzing, identifying, stating, referring to, dealing with, or in any way pertaining to.
- 11. The words "and" and "or" should be construed conjunctively or disjunctively as necessary to make a request inclusive rather than exclusive.

Filed 03/03/2008

- As applied to individuals, the words "Identify" and "Identity" means to 12. state the individual's full name, present or last known address and telephone number, present or last know employer, and present or last known business address and telephone number. As applied to Documents, ESI, and/or Things, the words "Identify" and "Identity" means to state the type of Document, ESI, and/or Thing, the date of the Document, ESI, and/or Thing, the names of the individuals who drafted, authored, or signed the Document, ESI, and/or Thing, the names of the individuals to whom the Document, ESI, and/or Thing, or a copy thereof was addressed or sent, a summary of the subject matter of the Document, ESI, and/or Thing, the number of pages of the Document, ESI, and/or Thing, the present whereabouts of the Document, ESI, and/or Thing, and the name and address of the custodian of the Document, ESI, and/or Thing. As applied to oral communications, state the name of the person making the communication and the name(s) of the person(s) present while the communication was made, and, where not apparent, the relationship of the person(s) present to the person making the communication, the date and place of the communication, and a summary of the subject matter of the communication.
- The singular form of a word shall include the plural and vice versa, and 13. terms in the present tense shall include terms in the past tense and vice versa.
- The words "any," "all," and "each" shall be construed to mean any, all, 14. each, and every.

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 1:

Documents, ESI, and/or Things the identification of which is sought by ArthroCare's First Set Of Interrogatories to Gyrus.

REQUEST FOR PRODUCTION NO. 2:

Documents, ESI, and/or Things that You reviewed, considered or relied upon in answering ArthroCare's First Set Of Interrogatories to Gyrus.

REQUEST FOR PRODUCTION NO. 3:

Five representative samples of each Gyrus Product.

REQUEST FOR PRODUCTION NO. 4:

Documents, ESI, and/or Things that describe Gyrus's past and present policies regarding the retention or destruction of Documents, files, ESI and things.

REQUEST FOR PRODUCTION NO. 5:

Documents, ESI, and/or Things sufficient to identify the officers, employees, and other personnel in any groups, divisions, or departments that have or had the responsibility for, or duties Related To, research, design, development, manufacture, operations, testing, sales, distribution and/or marketing of any Gyrus Product or any prototype thereof, including, without limitation, organizational charts, since 1999.

REQUEST FOR PRODUCTION NO. 6:

Documents, ESI, and/or Things sufficient to identify the officers, employees, and other personnel in any groups, divisions, or departments that have or had the responsibility for, or duties Related To, research, design, development, manufacture, operation, sales, distribution and/or marketing of any PlasmaCision-, PK-, or PlasmaKinetic-branded electrosurgical products or prototype thereof, from 1999 to the present, including, without limitation, organizational charts.

REQUEST FOR PRODUCTION NO. 7:

Documents, ESI, and/or Things Relating To the structures, features, operation and/or functionality of any Gyrus Product or any prototype thereof, made, used, sold, or offered for sale in the United States or imported into the United States, including, without limitation, schematics, drawings, diagrams, flow charts, specifications, user manuals, instructions for use (IFUs), product descriptions, catalogs, datasheets, brochures, presentations, reference manuals, and instruction manuals.

REQUEST FOR PRODUCTION NO. 8:

Documents, ESI, and/or Things Relating To the research, development, design, manufacture, production and/or testing of any Gyrus Product or any prototype thereof, made, used, sold, or offered for sale in the United States or imported into the United States, including, without limitation, any engineering notebooks, laboratory notebooks, test results, log books, record books, memoranda, progress reports, action item lists, analyses, design reviews, project reports, project history files, drawings, blueprints, sketches, schematics, specifications, diagrams, engineering change requests or orders, purchase requests or orders, vendor or subcontractor contracts, computer records, diaries, calendars, and any tests performed during qualification or repair of any Gyrus Product.

REQUEST FOR PRODUCTION NO. 9:

Documents, ESI, and/or Things Relating To clinical evaluation of, or FDA approval for, any Gyrus Product or any prototype thereof, made, used, sold, or offered for sale in the United States or imported into the United States, including, without limitation, any clinical plan, clinical studies, clinical data gathering, 510(k) submissions, Instructions for Use (IFU),

preparation of the IFU, FDA correspondence, communication with physicians, and physician evaluation of any Gyrus Product or any prototype thereof.

REQUEST FOR PRODUCTION NO. 10:

Documents, ESI, and/or Things Relating To clinical evaluation of or FDA approval for any Gyrus electrosurgical device or prototype thereof, made, used, sold, or offered for sale in the United States or imported into the United States since 1999, including, without limitation, any clinical plan, clinical studies, clinical data gathering, 510(k) submissions, IFUs, preparation of the IFU, FDA correspondence, communication with physicians, and physician evaluation of such electrosurgical devices or any prototype thereof, to the extent not otherwise produced in response to Request No. 9.

REQUEST FOR PRODUCTION NO. 11:

Documents, ESI, and/or Things Relating To any Opinion of Counsel, including without limitation, all Communications Relating thereto and all Documents considered, reviewed, relied upon or generated in the drafting or preparation of any Opinion of Counsel.

REQUEST FOR PRODUCTION NO. 12:

Documents, ESI, and/or Things that You consider, contend or believe constitute or might constitute prior art to the 882 Patent.

REQUEST FOR PRODUCTION NO. 13:

Documents, ESI, and/or Things Relating To any income or earnings from any Gyrus Products, including, without limitation, unit sales, revenues, cost of sales, gross margins, sales volumes, profits, and operating margins.

REQUEST FOR PRODUCTION NO. 14:

Documents, ESI, and/or Things Relating To the operation, design, features or configuration of electrodes of any Gyrus Product or prototype thereof, including but not limited to Documents, ESI, and/or Things Relating To the size and shape of each electrode, the number of electrodes, the arrangement of electrodes, the voltage, current, power, frequency, impedance, field densities, current paths, heat output of the electrodes, the location of the electrode relative to a handle or on a probe, the size and shape of the electrode recess, the insulation housing or surrounding of any electrode, the cutting and ablation mechanisms, coagulation mechanisms, and interaction with or effect on tissue.

REQUEST FOR PRODUCTION NO. 15:

Documents, ESI, and/or Things Relating To the presence of a fluid, including without limitation blood, saline, or electrically conducting fluid, in connection with the use or operation of any Gyrus Product or prototype thereof, including but not limited to its use as a current flow path, coolant, or irrigant, control of its flow direction or speed, its contact with the target tissue, its contact with any electrode, and its vaporization.

REQUEST FOR PRODUCTION NO. 16:

Documents, ESI, and/or Things Relating To marketing in the United States of any Gyrus Products or any prototypes thereof, made, used, sold, or offered for sale in the United States or imported into the United States including, without limitation, market requirements statements, marketing reports, market feedback reports, customer evaluations, market studies, market forecasts, market surveys, competitive analyses, market share data, customer needs studies, training materials, educational materials, product demonstrations, advertising materials,

REQUEST FOR PRODUCTION NO. 17:

Documents, ESI, and/or Things Relating To any importation, usage, sales, leases, placement, give-away, consignments, installations or offers to sell, lease, place, give-away, consign, or install in the United States any Gyrus Products or any prototype thereof, made, used, sold, or offered for sale in the United States or imported into the United States, including, without limitation, sales reports, sales forecasts, strategic plans, budgeting Documents, pricing policies, contracts with hospitals or buying groups, lost business reports, sales training materials, sales training courses, presentations to sales force, quotes, bids, purchase orders, invoices, shipping orders, guarantees, and warranties.

promotional materials, trade show materials, brochures, price lists, product press releases,

REQUEST FOR PRODUCTION NO. 18:

Documents, ESI, and/or Things Relating To any comparison, analysis, or study of any medical devices with or in light of any ArthroCare medical devices.

REQUEST FOR PRODUCTION NO. 19:

Documents, ESI, and/or Things Relating To the 882 Patent, the named inventors of the 882 Patent, ArthroCare, ArthroCare's products, or this litigation.

REQUEST FOR PRODUCTION NO. 20:

All Gyrus annual reports, required financial filings, and other financial statements, including without limitation, statements of operations, balance sheets, statements of changes in retained earning and notes thereto, whether prepared for internal or external purposes from 1999 to the present.

REQUEST FOR PRODUCTION NO. 21:

All financial statements (including, without limitation, monthly balances and income statements), for each Gyrus entity from 1999 to the present Relating To any Gyrus Product.

REQUEST FOR PRODUCTION NO. 22:

Documents, ESI, and/or Things Relating To profit margins or profit calculations, whether projected or realized, for any Gyrus Product.

REQUEST FOR PRODUCTION NO. 23:

Documents, ESI, and/or Things Relating To actual or forecasted sales of any Gyrus Product.

REQUEST FOR PRODUCTION NO. 24:

Documents, ESI, and/or Things Relating To the cost of sales, variable costs, incremental costs, overhead allocations, fixed costs, or other costs to research, develop, design, manufacture, market or sell any Gyrus Product.

REQUEST FOR PRODUCTION NO. 25:

Documents, ESI, and/or Things Relating To the costs of manufacture or production for any Gyrus Product.

REQUEST FOR PRODUCTION NO. 26:

Documents, ESI, and/or Things Relating To the market share possessed, projected or expected to be possessed by any Gyrus Product.

REQUEST FOR PRODUCTION NO. 27:

Documents, ESI, and/or Things Relating To Gyrus's competitors in the market for each of the Gyrus Products.

REQUEST FOR PRODUCTION NO. 28:

Documents, ESI, and/or Things Relating To the scope, validity or enforceability of the 882 Patent, including, without limitation, all Documents, ESI, and/or Things Relating To prior art patents or prior art patent applications, prior art publications, prior art sales, offers for sale or public uses, or any instances of alleged prior inventions.

REQUEST FOR PRODUCTION NO. 29:

Document s, ESI, and/or Things that support or refute Gyrus' contention that the Gyrus products do not infringe the 882 Patent.

REQUEST FOR PRODUCTION NO. 30:

Documents, ESI, and/or Things that support or refute Gyrus' contention that the 882 Patent is invalid and/or unenforceable.

REQUEST FOR PRODUCTION NO. 31:

Documents, ESI, and/or Things on which Gyrus may rely to refute ArthroCare's claim for damages in this action, or that support or refute Gyrus' contentions as to the damages to which ArthroCare would be entitled if the 882 Patent is held valid and infringed, including all documents relating to a lost profits or reasonable royalty analysis.

REQUEST FOR PRODUCTION NO. 32:

Documents, ESI, and/or Things Relating to any license agreements, transfers, potential license agreements, leases or the like, Relating to each Gyrus product.

MORRIS, NICHOLS ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#7014)
Karen Jacobs Louden (#2881)
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
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Attorneys for Plaintiff ArthroCare Corporation

OF COUNSEL:

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Kevin Kudlac Cabrach J. Connor WEIL, GOTSHAL & MANGES LLP 8911 Capital of Texas Highway Suite 1350 Austin, TX 78759 (512) 349-1930

February 4, 2008 1466523

CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that copies of the foregoing were caused to be served on February 4, 2008 upon the following in the manner indicated:

VIA ELECTRONIC MAIL and HAND DELIVERY

Richard L. Horwitz David E. Moore POTTER ANDERSON & CORROON LLP 1313 North Market Street Hercules Plaza – 6th Floor Wilmington, DE 19801

VIA ELECTRONIC MAIL

Darle M. Short Thomas J. Pardini Daniel A. Tanner, III Daniel M. Schneider Oliff & Berridge, PLC 277 S. Washington Street, Ste. 500 Alexandria, VA 22314

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

٧.

C.A. No. 07-729 (SLR)

Filed 03/03/2008

GYRUS MEDICAL, INC., GYRUS ENT, L.L.C., and GYRUS ACMI, INC.,

Defendants.

ARTHROCARE'S FIRST SET OF INTERROGATORIES TO GYRUS

Plaintiff ArthroCare Corporation ("ArthroCare") requests that Defendants Gyrus Medical, Inc., Gyrus ENT, L.L.C., and Gyrus ACMI, Inc. (collectively "Gyrus") respond separately, fully, in writing, and under oath, to these interrogatories within thirty (30) days from the date of service hereof pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, and in accordance with the following Definitions and Instructions.

DEFINITIONS

- "Gyrus Products" means each version or revision of the jPlasmaKnife, 1 Dissector PlasmaKnife, PlasmaCision Plasma Trissector, Plasma J-Hook, PlasmaSpatula, and PlasmaCision L-Hook Probe, any predecessor products, prototypes, retrofits, or upgrades of the foregoing, any product previously named any of the foregoing, and each of their respective systems, equipment, parts, and components.
- "ArthroCare" means plaintiff ArthroCare Corporation, its predecessors and successors, past and present parents, subsidiaries, divisions, affiliates, and other organizational or operating units of any of the foregoing, and all past and present directors, officers, employees, agents and representatives (including, attorneys and consultants) of any of the foregoing.

- 3. "Defendants," "Gyrus," "You," and "Your" means Defendants Gyrus Medical, Inc., Gyrus ENT, L.L.C., and/or Gyrus ACMI, Inc., and predecessors and successors, including without limitation its past and present parents, subsidiaries, divisions, affiliates, distributors, and other organizational or operating units of any of the foregoing, and all past and present directors, officers, employees, agents and representatives (including attorneys and consultants) of any of the foregoing.
- Rules of Civil Procedure and includes, but is not limited to, e-mail, attachments, files stored on any electronic media, copies of letters, notes and records of telephone conversations, sound recordings, intra-corporate communications, minutes, builetins, specifications, instructions, advertisements, literature, patents, patent applications, specification sheets and diagrams, work assignments, reports, memoranda, memoranda of conversations, notes, notebooks, drafts, data sheets, work sheets, contracts and agreements, memoranda of agreements, assignments, licenses, sublicenses, opinions and reports of experts and consultants, books of account, orders, invoices, statements, bills, checks and vouchers, brochures, photographs, drawings, charts, catalogs, pamphlets, magazines, copies of magazines, decals, world-wide web and/or internet postings, trade letters, notices and announcements, and press releases, and all other printed, written, recorded, taped, electronic, graphic, computerized printout or other tangible materials of whatever kind known to, or in the possession, custody, or control of Gyrus. A draft or nonidentical copy is a separate document within the meaning of this term.
- 5. "Electronically Stored Information" or "ESI" shall mean, consistent with the comprehensive meaning in Federal Rule of Civil Procedure 34, any writing, drawing, graph, chart, photograph, sound recording, image and other data or data compilations stored in any electronic media from which information can be obtained or translated into a reasonably usable form, other than a Document.

- 6. "Thing" shall mean, consistent with the comprehensive meaning in Federal Rule of Civil Procedure 34, any physical specimen or tangible item, other than a Document.
- 7. "Communication" means any form of oral or written interchange, whether in person, by telephone, by facsimile, by telex, by electronic mail (or email), or by any other medium.
- 8. "Opinion Of Counsel" means any opinions, searches, investigations, reviews, tests, or analyses, whether oral or in writing, that Relate To the scope, novelty, patentability, state of the art, validity, enforceability and/or infringement of the Patent-In-Suit or any related patents or any foreign counterparts.
 - 9. "Patent-In-Suit," or "882 Patent" means U.S. Patent No. 5,697,882.
- 10. "Concerning," "Relates To," "Relating To," "In Relation To," and "Related To," mean, without limitation, in whole or in part assessing, reporting, disclosing, constituting, comprising, consisting of, containing, concerning, regarding, embodying, reflecting, describing, discussing, analyzing, identifying, stating, referring to, dealing with, or in any way pertaining to.
- 11. The words "and" and "or" should be construed conjunctively or disjunctively as necessary to make a request inclusive rather than exclusive.
- state the individual's full name, present or last known address and telephone number, present or last know employer, and present or last known business address and telephone number. As applied to Documents, ESI, and/or Things, the words "Identify" and "Identity" means to state the type of Document, ESI, and/or Thing, the date of the Document, ESI, and/or Thing, the names of the individuals who drafted, authored, or signed the Document, ESI, and/or Thing, the names of the individuals to whom the Document, ESI, and/or Thing, or a copy thereof was addressed or sent, a summary of the subject matter of the Document, ESI, and/or Thing, the number of pages of the Document, ESI, and/or Thing, the present whereabouts of the Document, ESI, and/or

Page 23 of 98

- 13. The singular form of a word shall include the plural and vice versa, and terms in the present tense shall include terms in the past tense and vice versa.
- 14. The words "any," "all," and "each" shall be construed to mean any, all, each, and every.

INSTRUCTIONS

- 1. These interrogatories shall be deemed continuing, requiring Gyrus to supplement responses promptly in accordance with Rule 26(e) of the Federal Rules of Civil Procedure. Such supplemental responses shall be served as soon as is reasonably possible whenever Gyrus obtains different or additional information, knowledge, or belief Relating To these interrogatories.
- 2. If Gyrus has any good faith objection to any interrogatory or any part thereof, the specific nature of the objection and whether it applies to the entire interrogatory or to a part of the interrogatory shall be stated. If there is an objection to any part of an interrogatory, then the part objected to should be identified and a response to the remaining unobjectionable part should be provided.
- 3. If Gyrus withholds any responsive information based on a claim of privilege or any other claim of immunity from discovery, then for each item of information withheld, state the applicable claim (e.g. "attorney-client privilege," "work product doctrine," etc.), describe the general subject matter of the information withheld, and describe the facts giving rise to the claim in sufficient detail to permit ArthroCare to evaluate, and the Court to adjudicate, the validity of the claim.

INTERROGATORIES

INTERROGATORY NO. 1

For each Gyrus Product, state Gyrus's contentions, including the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraphs 13-17, 18-19. 22 and 28 of Defendants' Answer, Defenses, and Counterclaim ("Gyrus's Answer")) for such contentions, that the Gyrus Product has not infringed and does not infringe any of the claims of the Patent-In-Suit, including an identification of each claim that Gyrus contends is not infringed (regardless of Gyrus's contentions as to the validity of the Patent-In-Suit) and an element-byelement comparison of each claim with each Gyrus Product. For each element of any claims alleged to be absent from each such Gyrus Product, state whether any other feature, part, component, element, or step present in each such Gyrus Product performs substantially the same or a similar function as the allegedly omitted element or step (or if not, state why not) and identify each such feature, element, component, or process step and the function performed; state the factual basis, with reference to the specific page and line number of the prosecution history for the Patent-In-Suit, for any reliance on that prosecution history to support any noninfringement contention, including any reliance on the doctrine of prosecution history estoppel. A complete answer to this interrogatory also shall include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to Gyrus's non-infringement contentions.

INTERROGATORY NO. 2

Identify each electrosurgical instrument sold, offered for sale, imported, developed, or designed by or on behalf of Gyrus, including without limitation devices sold under or in connection with the PlasmaCision, PK, and PlasmaKinetic trade names and/or trademarks, by part number, indicated field of use, trade name, internal name, designation number, version, and dates of manufacture that are or have been made, used, sold, or offered for sale within the United States, or imported into the United States, by or on behalf of Gyrus.

INTERROGATORY NO. 3

Separately for each of the Gyrus Products, identify the persons who are primarily responsible for each of the following functions with respect to each product: design, development, manufacturing, advertising, sales, and distribution, and describe each such person's involvement with each product.

INTERROGATORY NO. 4

For each Gyrus Product, identify the persons who are most knowledgeable about: structure and operation of each product, the conception, design, and development of each product; the decision to manufacture and sell each product; and the testing of each product.

INTERROGATORY NO. 5

State Gyrus's contentions, if any, that the claims of the Patent-In-Suit are invalid for failure to comply with the requirements of 35 U.S.C. § 102, and include the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraphs 20, 21, 22, 29 and 30 of Gyrus's Answer) for such contentions, including but not limited to an identification of the prior art that Gyrus contends renders the claims of the Patent-In-Suit invalid, including a specific identification of where each limitation of each claim that Gyrus contends is invalid is found in the prior art reference; if a sale, offer for sale or prior use, then the identification of each claim limitation in the item that was the subject of the sale, offer for sale, or prior use should include an explanation with particularity that sets forth where each claim limitation specifically can be found in the particular item. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to Gyrus's § 102 contentions.

INTERROGATORY NO. 6

State Gyrus's contentions, if any, that the claims of the Patent-In-Suit are invalid for failure to comply with the requirements of 35 U.S.C. § 103, and include the complete factual

bases (including, but not limited to, the factual bases for the allegations of paragraphs 20, 21, 22, 29 and 30 of Gyrus's Answer) for any such contentions, including but not limited to the factual bases for Gyrus's contentions regarding the level of ordinary skill in the art at the time of the invention; whether Gyrus intends to combine any items of prior art to assert invalidity of any of the claims of the Patent-In-Suit, and if so, for each claim, state which items of prior art will be combined for each of the claims of the Patent-In-Suit; which portions of each item of prior art will be combined for each element of each of the claims, including a specific identification of where each limitation of each claims that Gyrus contends is invalid is found in the prior art reference; and, where, if at all, one of ordinary skill in the art would have found a teaching, suggestion or motivation to combine each such item of prior art; and the factual bases for Gyrus's contentions regarding any alleged absence of any of the objective indicia of non-obviousness such as commercial success, long felt need, failure of others, and skepticism of the patented invention. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to Gyrus's § 103 contentions.

INTERROGATORY NO. 7

State Gyrus's contentions, if any, that the claims of the Patent-In-Suit are invalid for any other reason than failure to comply with 35 U.S.C. §§ 102 and 103, and include the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraphs 20, 22, 29 and 30 of Gyrus's Answer) for any such contentions, including but not limited to, for failure to comply with the requirements of 35 U.S.C. § 112, including any contention that the claims are invalid for lack of enablement, failure to comply with the written description requirement and/or failure to comply with the best mode requirement. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to Gyrus's contentions set forth in response to this interrogatory.

INTERROGATORY NO. 8

State Gyrus's contentions, if any, Relating To Gyrus's allegation that any claims of the 882 Patent, as reexamined, are invalid and/or unenforceable because they are broader than the original claims of the 882 Patent and include the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraphs 22, 23, 29 and 30 of Gyrus's Answer) for any such contentions. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to Gyrus's contentions set forth in response to this interrogatory.

INTERROGATORY NO. 9

State Gyrus's contentions, if any, that ArthroCare's claims are barred under the doctrines of laches, estoppel, implied waiver and/or acquiescence and include the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraph 21 of Gyrus's Answer) for such contentions. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to such contentions.

INTERROGATORY NO. 10

State Gyrus's contentions, if any, that ArthroCare's claims are precluded by intervening rights and include the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraph 31 of Gyrus's Answer) for such contentions. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to such contentions.

INTERROGATORY NO. 11

State Gyrus's contentions, if any, that claims of the 882 Patent are unenforceable because of inequitable conduct and include the complete factual bases (including, but not limited

to, the factual bases for the allegations of paragraphs 22 and 32-34 of Gyrus's Answer) for such contentions. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to such contentions.

INTERROGATORY NO. 12

State Gyrus's contentions, if any, that ArthroCare's claims are precluded under 35 U.S.C. §§252 and/or 307(b) and include the complete factual bases (including, but not limited to, the factual bases for the allegations of paragraph 24 of Gyrus's Answer) for such contentions. A complete answer to this interrogatory shall also include an identification of all evidence that allegedly supports Gyrus's contentions and the person(s) most knowledgeable with respect to such contentions

INTERROGATORY NO. 13

Identify all opinions (oral or written) that were sought, rendered, or received by Gyrus, or anyone acting on Your behalf, relating to the patentability, scope, infringement, validity, or enforceability of the 882 Patent. A complete answer will include identifying whether such opinion was written or oral; an identification of the substance and subject matter(s) of each such opinion, including specific conclusions and opinions, as well as the facts set forth in the opinions; an identification of the date upon which each such opinion was sought, rendered, and received; an identification of all persons involved in seeking, rendering and receiving each such opinion; and an identification of whether Gyrus will rely on each such opinion.

MORRIS, NICHOLS ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiff ArthroCare Corporation

OF COUNSEL:

Jared B. Bobrow WEIL, GOTSHAL & MANGES LLP 201 Redwood Shores Parkway Redwood Shores, CA 94065 (650) 802-3000

Kevin Kudlac Cabrach J. Connor WEIL, GOTSHAL & MANGES LLP 8911 Capital of Texas Highway Suite 1350 Austin, TX 78759 (512) 349-1930

Dated: February 4, 2008 1466512

CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that copies of the foregoing were caused to be served on February 4, 2008 upon the following in the manner indicated:

VIA ELECTRONIC MAIL and HAND DELIVERY

Richard L. Horwitz
David E. Moore
POTTER ANDERSON & CORROON LLP
1313 North Market Street
Hercules Plaza — 6th Floor
Wilmington, DE 19801

VIA ELECTRONIC MAIL

Darle M. Short
Thomas J. Pardini
Daniel A. Tanner, III
Daniel M. Schneider
Oliff & Berridge, PLC
277 S. Washington Street, Ste. 500
Alexandria, VA 22314

Jack B. Blumenfeld (#1014)

IN THE UNITED STATES DISTRICT-COURT FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)
Plaintiff/Counterdefendant,))
v.))) Case No. 1:07-CV-00729-SLR
GYRUS MEDICAL, INC., GYRUS ENT, L.L.C., and GYRUS ACMI, INC.,)))
Defendants/Counterclaimants.) ·

SUPPLEMENTAL DECLARATION OF SIMON SHAW

I, Simon Shaw, hereby declare:

- 1. This Supplemental Declaration incorporates my January 22, 2008 Declaration in this matter.
- 2. Under the UK Takeover Code, when one company procures another company, the bid is announced publicly and thereafter third parties have a set time period to place a higher bid.
- 3. Paragraph 10 of the Implementation Agreement between Olympus and Gyrus Group provides that Gyrus Group would not solicit or initiate the submission of competing proposals, or enter into negotiations with a third party offering a competing proposal. The reason that paragraph 10 was included in the Implementation Agreement was because Olympus and Gyrus Group were cooperating with one another to complete the acquisition.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on February 28, 2008.

Simon Shaw

OLIFF & BERRIDGE, PLC

ATTORNEYS AT LAW

December 20, 2007

277 South Washington Street ALEXANDRIA, VIRGINIA 22314

TELEPHONE: (703) 836-6400
FACSIMILE: (703) 836-2787
E-MAIL: EMAIL@OLIFF.COM
WWW.OLIFF.COM

By Facsimile

Jared B. Bobrow, Esquire WEIL, GOTSHAL & MANGES, LLP 201 Redwood Shores Pkwy Redwood Shores, CA 94065

Re:

ArthroCare Corp. v. Gyrus Medical, Inc., et al.

Case No. 07-729

Dear Mr. Bobrow:

As you may know, we represent the three defendants in the above-referenced case. We write regarding a preliminary matter.

It is our understanding that your firm represents Olympus in its ongoing efforts to acquire Gyrus Group PLC, which is the parent corporation of the three defendants. During your firm's representation of Olympus in that regard, your firm obtained confidential information of Gyrus Group PLC and the three defendants in the case, including confidential information regarding Gyrus's products and Gyrus's intellectual property matters. Your firm also interviewed Gyrus Group PLC's chief intellectual property officer one day before filing the complaint.

Based on our information, it appears that it is a clear conflict of interest for Weil, Gotshal & Manges to represent ArthroCare Corporation in this case and to have access to and review confidential information of defendants and their parent corporation, which information may be relevant to issues in this case. Thus, it appears that your firm should recuse itself from this case. Please advise whether your firm will do so, and if not, please provide the reasons why your firm believes its recusal is not necessary.

We look forward to receiving your response by December 31. Please contact me if you would like to discuss this issue or anything else regarding this case.

Finally, we also want to take this opportunity to thank you for the courtesy of consenting to our request for a thirty day extension of the due date for defendants to respond to the complaint.

Very truly yours,

Darle M. Short

DMS/mdw

cc: David E. Moore, Esquire (by facsimile)

Jack B. Blumenfeld, Esquire (by facsimile)

12/31/2007 16:20 FAX 5125270798

WEIL GOTSHAL

Ø 002

WEIL, GOTSHAL & MANGES LLP

BYTH CAPITAL OF TEXAS HIGHWAY BUILDING ONE, SUITE 1350 AUSTIN, TEXAS 78759 (512) 349-1930 FAX: (512) 527-0798

BOSTON RRUSSELS BUDAPEST DALLAS FRANKFURT HOUSTON LONDON IMAIM MUNICH NEW YORK PARIS PRAGUE PROVIDENCE SHANGHAL SILICON VALLEY SINGAPORE WARRAW WASHINGTON, D.C.

WAITER'S DIRECT LINE 650 802 3034 jared Robrow

December 31, 2007

BY FAX & MAIL

Darle M. Short, Esq. Oliff & Berridge, PLC 277 South Washington Street Alexandria, Virginia 22314

> ArthroCare Corp. v. Gyrus Medical, Inc., et al., 07-729 Re:

Dear Mr. Short:

cc;

Due to the holiday and vacation schedules, we will respond to your December 20, 2007, letter in the new year.

> Sincerely, ned born / Sypenissian Clause

fared/Bobrow

Jack B. Blumenfeld, Esq.

277 SOUTH WASHINGTON STREET ALEXANDRIA, VIRGINIA 22314

> TELEPHONE: (703) 836-6400 FACSIMILE: (703) 836-2787 E-MAIL: EMAIL@OLIFF.COM WWW.OLIFF.COM

OLIFF & BERRIDGE, PLC

ATTORNEYS AT LAW

January 10, 2008

Jared B. Bobrow, Esquire WEIL, GOTSHAL & MANGES, LLP 201 Redwood Shores Pkwy Redwood Shores, CA 94065 By Facsimile

Re:

ArthroCare Corp. v. Gyrus Medical, Inc., et al.

Case No. 07-729

Dear Mr. Bobrow:

We still have not received a substantive response to our December 20, 2007 letter, which requested a response by December 31. While we are cognizant of the intervening holiday season as discussed in your December 31 letter, we believe, unless you explain otherwise, that sufficient time has passed for ArthroCare and Weil, Gotshal to fully consider our letter.

In addition, we have uncovered additional facts that seemingly support Weil, Gotshal's disqualification, including that Weil, Gotshal signed a Common Interest Agreement between Olympus Corporation and Gyrus Group, PLC, on behalf of Olympus Corporation, and that Weil, Gotshal received specific confidential information about the allegedly infringing products, including marketing plans and strategy, on an attorney eyes only basis due to its representation of Olympus.

Please advise when we can telephone you tomorrow, and provide the number we should call, to discuss, pursuant to Local Court Rule 7.1.1, a possible motion to disqualify Weil, Gotshal.

Very truly yours,

Darle M. Short

DMS/mdw

cc: David E. Moore, Esquire (by facsimile)

Jack B. Blumenfeld, Esquire (by facsimile)

tack B. Didilicinota, Esquito (of tacsimila)

January 11, 2008

Darle M. Short Oliff & Berridge, PLC 277 South Washington Street Alexandria, Virginia 22314

Re:

ArthroCare Corp. v. Gyrus Medical Inc., et al.

Case No.: 07-729

Dear Mr. Short:

I am writing in response to your letters of December 20, 2007 and January 10, 2008 to Jared Bobrow concerning the above-identified litigation ("the Gyrus Litigation"). I am writing to you in my role as counsel for the firm – I am not working on either the Gyrus Litigation or the potential acquisition of Gyrus Group PLC by Olympus ("the Gyrus Acquisition").

As you note in your December 20, 2007 letter, Weil, Gotshal & Manges LLP ("WGM") is counsel to Olympus ("the WGM Olympus team") with respect to the Gyrus Acquisition. As such, WGM is adverse to Gyrus Group PLC and Gyrus Group PLC is not, and has never been, a client of WGM. In the Gyrus Litigation, WGM is adverse to the various Gyrus entities that are named defendants in the case ("the WGM ArthroCare team"). As such, there is no conflict of interest with respect to these representations, both of which are adverse to Gyrus.

Page 41 of 98

Darle M. Short January 11, 2008 Page 2

In your January 10, 2008 letter you claim that WGM received "specific confidential information about the allegedly infringing products." As you are undoubtedly aware, on November 16, 2007, Gyrus's counsel (Allen & Overy) was asked to identify any confidential information related to the Gyrus Litigation that had been provided to WGM. Prior to your letter of January 10, 2008, no such information had been identified and, based on our review, we do not believe that we have such information.

Furthermore, as requested by Gyrus's counsel (Allen & Overy), on November 16, 2007, a Solicitor's undertaking was provided by the WGM Olympus Team to Gyrus's counsel (Allen & Overy) concerning any Gyrus confidential information related to the Gyrus Litigation provided to the WGM Olympus Team. Indeed, at the same time, Gyrus's counsel was informed that the WGM Olympus Team sought to ensure that it did not receive any confidential Gyrus information related to the Gyrus Litigation. It is our understanding that prior to that undertaking (and the accompanying affirmative statement concerning attempting to not obtain such confidential information) Gyrus had not provided the WGM Olympus Team any confidential information related to the Gyrus Litigation. Indeed, Gyrus's counsel was asked to identify any such information that had been provided and none was identified. Accordingly, if any Gyrus confidential information related to the Gyrus Litigation was provided to WGM it was after the Solicitor's undertaking; after Gyrus's counsel was informed that the WGM Olympus Team did not want to obtain any Gyrus confidential information related to the Gyrus Litigation; and after Gyrus was aware that WGM represented ArthroCare in the Gyrus Litigation. In these circumstances a party cannot knowingly provide information and then claim its provision of such information constitutes a basis for disqualification.

In any event, even if Gyrus did provide confidential information related to the Gyrus Litigation to the WGM Olympus Team - which we do not believe to be the case the Solicitor's undertaking of November 16, and its implementation, ensure that such information will not be available to the WGM ArthroCare Team. Pursuant to the undertaking, WGM has in place an ethical wall to prevent, among other things, the WGM ArthroCare Team from obtaining any information relating to Gyrus (or to the potential acquisition by Olympus) that was obtained by the WGM Olympus Team. Moreover, the ethical wall prohibits the WGM ArthroCare Team from discussing that litigation or the potential acquisition of Gyrus by Olympus (or any information related to either matter) with the WGM Olympus Team (and vice-versa). As such, any Gyrus confidential information that may have been obtained by the WGM Olympus Team has not been, and will not be, shared with, or available to, the WGM ArthroCare Team.

Darle M. Short January 11, 2008 Page 3

Moreover, in your January 10, 2008 letter you point out that a Common Interest Agreement exists between Olympus and Gyrus. The final paragraph of that Agreement provides that it "shall not be used in any fashion against the signatories [] other than as set forth in [the] Agreement." It further states that "[b]y way of example and not limitation, it shall not be used offensively or defensively in any litigation between signatories to this Agreement (other than as covered by this Agreement) involving any issue relating to or deriving from this transaction, nor will any of the parties claim that any counsel is disqualified in such litigation by reason of the joint defense effort." As such, and given the sequence of events recited above, it would be improper for Gyrus to offensively use the Common Interest Agreement to attempt to disqualify the WGM ArthroCare Team from the Gyrus Litigation.

Given all of the foregoing, WGM will not be withdrawing from its representation of ArthroCare in the Gyrus Litigation. If you have additional information that relates to this situation or that you believe indicates there is a conflict, please let me know and I will consider it immediately.

Finally, I note that you have requested a time for a Local Court Rule 7.1.1 conference on Friday. I am unavailable for such a conference on Friday, but could be available on Monday. If you believe it imperative to proceed today, Jared Bobrow and/or Kevin Kudlac would be available this afternoon.

Sincerely,
WEIL, GOTSHAL & MANGES LLP
By:
Richard J. Davis

Jared Bobrow CC: Kevin Kudlac



FORM 10-Q

ARTHROCARE CORP - ARTC

Filed: October 29, 2007 (period: September 30, 2007)

Quarterly report which provides a continuing view of a company's financial position

Our headcount at September 30, 2007 was 1,057, an increase of 20.0 percent from 881 at December 31, 2006 and an increase of 22.8 percent from 861 at September 30, 2006. Headcount increases are primarily attributable to increases in manufacturing personnel in Costa Rica and additions of personnel in sales and marketing and research and development.

Results of Operations and Financial Condition

Comparison of the three and nine months ended September 30, 2007 to the three and nine months ended September 30, 2006 (in thousands, unless otherwise noted):

	Three Months Ended September 30,			Nine Months Ended September 30,				
	2007 2006		200	7	2006			
Revenues:								
Product sales	\$ 75,492	96.2%	\$ 62,117	96.0%	\$223,098	96.3%	\$186,196	96.4%
Royalties, fees, and other	2,969	3.8%	2,577	4.0%	8,648	3.7%	6,985	3.6%
Total revenues	78,461	100.0%	64,694	100.0%	231,746	100.0%	193,181	100.0%
Cost of product sales	21,200	27.0%	19,932	30.8%	63,659	27.5%	57,394	29.7%
Gross profit	<u>57,261</u>	73.0%	44,762	69.2%	168,087	72.5%	135,787	70.3%
Operating expenses:								
Research and development	6,519	8.3%	5,625	8.7%	19,608	8.4%	17,953	9.3%
Sales and marketing	29,531	37.7%	20,369	31.5%	89,137	38.5%	65,069	33.7%
General and administrative	6,023	7.7%	5,014	7.7%	18,332	7.9%	15,452	8.0%
Amortization of intangible assets	1,753	2.2%	1,784	2.8%	5,588	2.4%	5,324	2.8%
Total operating expenses	43,826	55.9%	32,792	50.7%	132,665	57.2%	103,798	53.7%
Income from operations Interest and other income (expense),	13,435	17.1%	11,970	18.5%	35,422	15.3%	31,989	16.6%
net	1,010	1.3%	(440)	(0.7)%	1,815	0.8%	<u>(761</u>)	(0.4)%
Income before income tax provision	14,445	18.4%	11,530	17.8%	37,237	16.1%	•	16.2%
Income tax provision	3,323	4.2%	2,854	4.4%	8,565	3.7%	7,720	4.0%
Net income	<u>\$ 11,122</u>	14.2%	\$ 8,676	13.4%	<u>\$ 28,672</u>	12.4%	\$ 23,508	12.2%

Revenues

Product sales consist primarily of sales of disposable devices and controllers. Product sales for the quarter ended September 30, 2007 were \$75.5 million, compared to \$62.1 million for the quarter ended September 30, 2006. Product sales for the nine months ended September 30, 2007 were \$223.1 million, compared to \$186.2 million for the nine months ended September 30, 2006.

(12) EX PARTE REEXAMINATION CERTIFICATE (5647th)

United States Patent

Eggers et al.

(10) Number:

US 5,697,882 C1

(45) Certificate Issued:

Jan. 9, 2007

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND **ABLATION**

(75) Inventors: Philip E. Eggers, Dublin, OH (US); Hira V. Thapliyal, Los Altos, CA (US)

Assignce: Arthrocare Corporation, Sunnyvale, CA (US)

Reexamination Request:

No. 90/006,607, Apr. 18, 2003

Reexamination Certificate for:

5,697,882 Patent No.: Dec. 16, 1997 Issued: Appl. No.: 08/561,958 Nov. 22, 1995 Filed:

Certificate of Correction issued Apr. 7, 1998.

Certificate of Correction issued Aug. 25, 1998.

Certificate of Correction issued May 2, 2000.

Related U.S. Application Data

- (63) Continuation-in-part of application No. 08/485,219, filed on Jun. 7, 1995, which is a continuation-in-part of application No. PCT/US94/05168, filed on May 10, 1994, which is a continuation-in-part of application No. 08/059,681, filed on May 10, 1993, now abandoned, which is a continuation-in-part of application No. 07/958,977, filed on Oct. 9, 1992, now Pat. No. 5,366,443, which is a continuation-in-part of application No. 07/817,575, filed on Jan. 7, 1992, now abandoned.
- (51) Int. Cl. A61B 18/14 (2006.01)(2006.01)A61B 17/20
- (52) U.S. Cl. 604/114; 604/22

Field of Classification Search 604/22, 604/28, 43, 48, 49, 113, 114, 41; 606/27-32, 606/35, 38, 41, 45-50

See application file for complete search history.

References Cited (56)

U.S. PATENT DOCUMENTS

(Continued)

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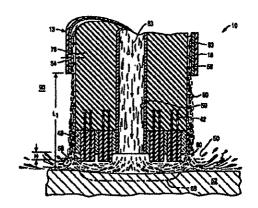
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(Continued)

Primary Examiner-Michael J Hayes

ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode and the electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the active and return electrodes.



US 5,697,882 C1 Page 2

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EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 2-13, 15, 16, 21, 22, 25, 27 and 32-36 is confirmed.

Claims 1, 14, 17-20, 23, 24 and 26 are cancelled.

Claims 28, 37, 41, 45-52 and 54-56 are determined to be patentable as amended.

Claims 29, 30, 31, 38-40, 42, 43, 44 and 53, dependent on an amended claim, are determined to be patentable.

New claims 57-67 are added and determined to be patentable.

28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to 35 the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to [ablate] cause molecular disassociation or disintegration of the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the [ablated] body structure

37. The method of claims [23] 1 or [48] 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating 50 matrix comprising an inorganic material.

- 41. The method of claims 28 [and] or 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.
- 45. The method of claims [23] I or [55] 33 wherein the 55 density of the vapor layer is less than about 10²⁰ atoms/cm³.
- 46. The method of [claims 23 or 50] claim 30 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.
- 47. The method of claims 23 or 48 claim 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

 60 electrically conductive fluid comprises isotonic saline.

 61 electrically conductive fluid comprises isotonic saline.

 62 electrically conductive fluid comprises isotonic saline.

 63 electrically conductive fluid comprises isotonic saline.

 64 electrically conductive fluid comprises isotonic saline.

 65 electrically conductive fluid comprises isotonic saline.
- 48. The method of [claims 48 or 52] claim 28 wherein the high frequency voltage is at least 200 volts peak to peak.
- 49. The method of claims 48 or 521 claim 28 wherein the 65 from 0.0 to 2.0 mm. high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

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- 50. The method of claims [48] 26 or [52] 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.
- 51. The method of claims [48] 26 or [52] 28 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.
- 52. The method of [claims 23 or 48] claim 28 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.
 - 54. The method of [claims 23 or 48] claim 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.
 - 55. The method of [claims 23 or 48] claim 28 wherein the target site is a tumor within or on the patient's body.
 - 56. The method of claims [48] 26 or [52] 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.
 - 57. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to

the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and not in contact with the target site and then moving said electrode terminal and said thin layer towards said target site wherein the discharge of energy to the target site in contact with the vapor layer is induced.

- 58. The method of claim 57 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.
- 59. The method of claim 57 wherein at least a portion of the energy is in the form of energetic electrons.
- 60. The method of claim 57 wherein the high frequency voltage is at least 200 volts peak to peak.
- 61. The method of claim 57 wherein the voltage is in the range from 500 to 1400 volts peak to peak.
- 62. The method of claim 57 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.
- 63. The method of claim 57 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.
- 64. The method of claim 57 wherein the distance between the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.
- 65. The method of claim 57 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 2 mVcm
- 66. The method of claim 57 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.
- 67. The method of claim 57 wherein the electrode height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

EXHIBIT 20

I hereby certify that this correspondence is being deposited with the United States Postal Service via Express Mail No. ER 824821855 US to Addressee service Under 37 CFR 1.10 on the date indicated below in an envelope a

PATENT

Attorney Docket No.: RE-02

Commissioner for Patents, Alexandria VA 22313-1450

a dorille 2005

Michelle Nicely

4660 U.S. PTO

.94/18/05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: ·

PHILIP E. EGGERS et al.

Application No. 90/006,607

Reexamination of Patent No.: 5,697,882

Issued: December 16, 1997

For: SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND

ABLATION

Assignee: ArthroCare Corporation

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Examiner: M. Hayes

Art Unit: 3763

REPLY TO NON-FINAL OFFICE

ACTION

Sir:

This is in response to the Office Action mailed February 18, 2005.

Introductory Comments begin on page 2.

Amendments begin on page 3.

Remarks begin on page 11.

Closing comments are on page 35.

INTRODUCTORY COMMENTS

Patentee provides the following background information relating to U.S. Patent No. 5,697,882 (hereafter the "882 Patent").

Lawsuit Between Patentee And Smith & Nephew Over The '882 Patent

In 2001, Patentee ArthroCare Corp. ("ArthroCare") commenced a patent infringement lawsuit against Smith & Nephew in the District of Delaware, Civil Action No. 01-504-SLR. During the trial, Patentee asserted, inter alia, that Smith & Nephew had infringed Claims 13, 17, and 54 of the '882 Patent. Smith & Nephew asserted, inter alia, that these Claims were invalid in light of prior art that is the subject of this reexamination, namely, U.S. Patent No. 5,122,138 to Manwaring (the "Manwaring Patent") and an article by Cornelis J. Slager et al. entitled "Vaporization of Atherosclerotic Plaques by Spark Erosion," Journal of the American College of Cardiology, Vol. 5, No. 6, June 1985, at 1382-86 (the "Slager Article"). During the trial, Smith & Nephew's experts, Dr. Kenneth Taylor and Dr. Kim Manwaring (the named inventor of the Manwaring Patent) testified concerning this prior art. After an eight-day trial, the jury returned a verdict finding, inter alia, that Claims 13, 17, and 54 were infringed and were not invalid. The district court entered final judgment on June 20, 2003 based upon the jury's verdict. Following the verdict, the district court denied Smith & Nephew's post-trial motion for judgment as a matter of law. Thereafter, the district court entered an injunction against Smith & Nephew. Smith & Nephew has appealed the judgment to the United States Court of Appeals for the Federal Circuit, Nos. 04-1323, -1487. The parties have completed briefing and oral argument on the appeal.

AMENDMENTS

Please make the following amendments to the claims. The amendments provided herein are in marked up form vis-à-vis the claims in effect at the time of filing this reexamination proceeding.

1. (original) A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

- 2. (original) The method of claim 1 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.
- 3. (original) The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm².
- 4. (original) The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².
- 5. (original) The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0 mm.
- 6. (original) The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.
- 7. (original) The method of claim 2 wherein the electrode terminals comprises a material with a

relatively low thermal conductivity.

- 8. (original) The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, tungsten, platinum, aluminum and tantalum.
- 9. (original) The method of claim 2 wherein the return electrode has a distal end positioned proximal to the electrode array.
- 10. (original) The method of claim 2 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.
- 11. (original) The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.
- 12. (original) The method of claim 11 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.
- 13. (original) The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.
- 14. (original) The method of claim 1 wherein at least a portion of the energy is in the form of energetic electrons.
- 15. (original) The method of claim 14 wherein the energy of the energetic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.
- 16. (original) The method of claim 14 wherein the energy evolved by the energetic electrons is greater than 3 eV.

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- 17. (original) The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.
- 18. (original) The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.
- 19. (original) The method of claim 1 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.
- 20. (original) The method of claim 1 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.
- 21. (original) The method of claim 1 wherein the distance between the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.
- 22. (original) The method of claim 1 wherein the electrode terminal and the return electrode are of comparable size and comprise a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body structure.
- 23. (original) The method of claim 1 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 2 mS/cm.
- 24. (original) The method of claim 1 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.
- 25. (original) The method of claim 1 wherein the electrode height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

26. (original) A method for applying energy to a target site on a patient body structure comprising: providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being in the range from 500 to 1400 volts peak to peak.

- 27. (original) The method of claim 26 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak.
- 28. (original) A method for applying energy to a target site on a patient body structure comprising:

 providing an electrode terminal and a return electrode electrically coupled to a high
 frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

29. (original) The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal; and

inducing the discharge of photons to the target site in contact with the vapor layer.

30. (original) The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface; and

inducing the discharge of energetic electrons to the target site in contact with the vapor layer.

- 31. (original) The method of claim 28 wherein the depth of necrosis is 0 to 400 microns.
- 32. (original) A method for applying energy to a target site on a patient body structure comprising: providing an active electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that cause the breakdown of tissue through molecular dissociation or disintegration.

33. (original) The method of claim 32 wherein the generating step comprises: providing a return electrode electrically coupled to a high frequency voltage source; applying a high frequency voltage between the electrode terminal and the return electrode; and

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal.

- 34. (original) The method of claim 33 further comprising developing a film layer of vapor between the active electrode and the body structure at the target site.
- 35. (original) The method of claim 33 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.
- 36. (original) The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.
- 37. (amended) The method of [claims 23 or 48] claims 1 or 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically

isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

- 38. (original) The method of claim 37 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.
- 39. (original) The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.
- 40. (original) The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.
- 41. (original) The method of claims 28 and 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.
- 42. (original) The method of claim 41 wherein the generating step comprises:

 providing a return electrode electrically coupled to a higher frequency voltage source;

 applying a high frequency voltage between the return electrode and the array of electrode terminals; and
- vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.
- 43. (original) The method of claim 42 further comprising developing a film layer of vapor between one or more of the electrode terminals and the target site.
- 44. (original) The method of claim 42 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.
- 45. (amended) The method of [claims 23 or 55] claims 1 or 33 wherein the density of the vapor layer is less than about 10²⁰ atoms/cm³.

- 46. (amended) The method of [claims 23 or 50] claims 1 or 30 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.
- 47. (amended) The method of [claims 23 or 48] claims 1 or 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².
- 48. (amended) The method of [claims 48 or 52] claims 26 or 28 wherein the high frequency voltage is at least 200 volts peak to peak.
- 49. (amended) The method of [claims 48 or 52] claims 26 or 28 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.
- 50. (amended) The method of [claims 48 or 52] claims 26 or 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.
- 51. (amended) The method of [claims 48 or 52] claims 26 or 28 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.
- 52. (amended) The method of [claims 23 or 48] claims 1 or 28 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.
- 53. (original) The method of claim 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.
- 54. (amended) The method of [claims 23 or 48] claims 1 or 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.
- 55. (amended) The method of [claims 23 or 48] claims 1 or 28 wherein the target site is a tumor

within or on the patient's body.

56. (amended) The method of [claims 48 or 52] <u>claims 26 or 28</u> wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

REMARKS

Status of Claims

Claims 1-56 are subject to this reexamination. The Office Action indicated that claims 2-12, 15, 16, 22, 32-36, 41-45, 51 and 56 are patentable and/or confirmed. The Office Action indicates that claims 1, 13, 14, 17-21, 23-31, 37-40, 46-50 and 52-55 are rejected.

Claims 37, 45-52, and 54-56 have been amended by this reply solely to correct inadvertent typographical errors by Patentee in seeking a Certificate of Correction. In accordance with the MPEP § 2250 (II), Patentee has provided the amendments in marked up form vis-à-vis the claims in effect at the time of filing this reexamination. In particular, the claims are marked up vis-à-vis the Certificate of Correction that issued on May 2, 2000. No claims have been cancelled by this reply.

For the reasons discussed below, Patentee respectfully requests reconsideration and withdrawal of the rejections of the claims.

35 U.S.C. § 102

Claim Rejections Under 35 U.S.C. § 102 Based On Manwaring

According to the Office Action, independent claims 1 and 28 and dependent claims 13, 14, 19, 20, 23, 24, 29, 30, 46, 47, and 50 stand rejected under 35 U.S.C. § 102 based the Manwaring Patent. Patentee respectfully disagrees. As set forth below, the Manwaring Patent fails to disclose each and every limitation of the claims and, as a result, cannot anticipate.

A. Claim 1: Independent method Claim 1 of the '882 Patent includes claim limitations that are not disclosed in the Manwaring Patent. Claim 1 requires, among other things, that a high frequency voltage first vaporize electrically conducting fluid and, thereafter, that energy be discharged to the target site on the patient that is in contact with the vapor layer.

It is clear from the claim language itself and from the '882 Patent's specification that the method of claim 1 requires vaporization of electrically conducting fluid followed by energy discharge to the target site in contact with the vapor layer. Claim 1 expressly provides that the high frequency voltage "induce[s] the discharge of energy to the target site in contact with the vapor layer." By referring to "the vapor layer," Claim 1 plainly provides that the claimed vapor layer must exist before the claimed energy discharge occurs. Moreover, the specification repeatedly describes the inventive method as one in which vaporization of the electrically conducting fluid occurs before energy discharge to the patient target site in contact with the vapor layer. In the Summary of the Invention section, the '882 Patent explains that the electric field "vaporizes" the electrically conducting fluid "and then ionizes the vapor layer." '882 Patent, col. 4:50-54. Later in the Summary of the Invention, the '882 Patent again explains that the creation of a "vaporized layer" is "followed by" the emission of photons or electrons. Id., col. 5:47-57. Similar descriptions of the required sequence are set forth in the Description of the Preferred Embodiment, See, e.g., id., col. 10:55-11:3; col. 11:53-67.

Those of ordinary skill understand Claim 1 to require that vaporization be followed by energy discharge. During the trial against Smith & Nephew in Delaware, both of Smith & Nephew's experts - Dr. Taylor and Dr. Manwaring - agreed that Claim 1 of the '882 Patent claims a method in which vaporization of the electrically conducting fluid is followed by energy discharge to the target site in contact with the vapor layer, Exh. A (Trial Tr. at 905-06 (Manwaring) and 1433 (Taylor)).

Unlike Claim 1, the Manwaring Patent does not disclose vaporization of electrically conducting fluid followed by energy discharge to the target site on the patient in contact with a vapor layer. In fact, the Manwaring Patent describes the opposite sequence of steps. The Manwaring Patent expressly provides that the electric field first causes energy discharge in the form of sparks and that this sparking leads to high temperature vaporization of fluid, thereby treating tissue. Manwaring Patent, col. 6:50-63. The Manwaring Patent states unequivocally that "RF sparking" (i.e., energy discharge) is "followed by fluid vaporization." Id. (emphasis added). Thus, the Manwaring Patent does not disclose the method of Claim 1 and, therefore cannot anticipate Claim 1 or any of the claims that depend thereon.

1. Claim 13: Claim 13 depends on Claim 1. In addition to the limitations of Claim 1, Claim 13 also requires that a portion of the induced energy be "in the form of photons having a wavelength in the ultraviolet spectrum." The Manwaring Patent simply does not disclose these limitations. The Manwaring Patent merely discloses "sparking." Nothing in the Manwaring Patent states or suggests that the sparks include ultraviolet photons. Indeed, ultraviolet light is never mentioned in the Manwaring Patent. This is confirmed by the Rebuttal Expert Witness Report prepared by Dr. S. Nahum Goldberg, who opined that the Manwaring Patent "does not disclose the discharge of photons in the ultraviolet spectrum" and stated that "there is no evidence of which I am aware which indicates that the device disclosed in the Manwaring '138 Patent discharged photons in the ultraviolet spectrum." See accompanying Declaration of John T. Raffle at 2.

The Office Action states at page 2 that "The sparking disclosed by Manwaring inherently results in the inducement of photons having a wavelength in the ultraviolet spectrum due to the vaporization of saline and contains energetic electrons as evidenced by the sparking. Eggers (5,697,882) states that photons with wavelength in the ultraviolet spectrum are formed from saline vaporization (4:46-63, 11:12-18)." Patentee respectfully submits that the '882 Patent neither states nor suggests that ultraviolet emission is inherent in saline vaporization. To begin with, the cited passages never state that mere vaporization of saline is sufficient to cause the emission of ultraviolet light. Saline, like water, can be vaporized without creating any excited species. Moreover, the '882 Patent expressly provides that ultraviolet photon emission occurs "under optimal conditions," not under all conditions. '882 Patent, col. 10:59-11:3; col. 21:30-39. The '882 Patent further explains that there are a number of "conditions" for forming a vapor layer and inducing the discharge of

energy from the plasma in the vapor layer. '882 Patent, col. 11:4-12. The Manwaring Patent does not address each of these conditions, including the issue of asperities or sharp edges on the electrode surface and applied voltage. In fact, the Manwaring Patent is silent on the voltage applied when the Manwaring device is used. In the context of the '882 Patent, the passages cited by the Examiner simply mean that ultraviolet emission occurs when the claimed invention is practiced, not necessarily whenever sparking occurs in saline. Patentee submits that it would be improper to use the inventor's disclosure of his invention to render the claims unpatentable.

In addition, experimental evidence demonstrates that sparking in saline does not inherently emit ultraviolet photons. The accompanying declaration of Kenneth Stalder, a Ph.D. physicist, shows that ultraviolet light emission is not an inherent property of sparking in saline. In fact, Dr. Stalder measured light emission from sparking in isotonic saline and found that the sparks do not always generate ultraviolet photons. Because ultraviolet light emission is not "necessarily" produced by sparking in saline, the Manwaring Patent does not inherently disclose it. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991); In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (disclosure is not inherent if it is merely probable or possible).

2. Claim 14: Claim 14 depends on Claim 1. In addition to the limitations of Claim 1, Claim 14 also requires that a portion of the energy be "in the form of energetic electrons." The Manwaring Patent simply does not disclose these limitations. The Manwaring Patent merely discloses "sparking." Nothing in the Manwaring Patent states or suggests that the sparks include "energetic electrons." Indeed, energetic electrons are never mentioned in the Manwaring Patent, Moreover, unlike the '882 Patent, the Manwaring Patent is silent concerning the applied voltage used in the system and is silent concerning the energy levels of electrons near the target tissue site.

The Office Action states at page 2 that the sparking disclosed by the Manwaring Patent necessarily contains energetic electrons. Patentee respectfully disagrees. While a spark will include electrons, there is nothing in the Manwaring Patent which states or suggests that the electrons are "energetic" as described in the '882 Patent. The '882 Patent describes the energetic electrons as having 4 to 5 electron volts. '882 Patent, col. 11:27-30, col. 12:25-27. Nothing in the Manwaring Patent states that the electrons possess this much energy. Moreover, the '882 Patent makes clear that the emission of energetic electrons is not inherent. Rather, the '882 Patent states that ionization in the vapor layer will induce the discharge of energetic electrons "under optimal conditions," not under all conditions. '882 Patent, col. 10:60-11:3; col. 21:30-37. Finally, as set forth in the

Declaration of Dr. Stalder, visible sparks can be generated in isotonic saline by electrons that have energy levels substantially below 4 to 5 electron volts. According to Dr. Stalder, sodium atoms will emit visible light when bombarded by electrons having energies as low as 2.1 electron volts. Because the Manwaring Patent is silent concerning the applied voltage, and because there is no discussion of the energy levels of the electrons near the target site, the Manwaring Patent does not disclose electrons having energy levels equal to or greater than 4 to 5 electron volts.

Claim 46: Claim 46 depends on Claim 1. In addition to the limitations of Claim 1, Claim 46 also requires that the electrode terminal be "configured to promote bubble nucleation causing the formation of the vapor layer." The Manwaring Patent does not disclose these additional limitations.

The '882 Patent explains that electrode terminals can be configured to promote bubble nucleation by, for example, producing sharp edges and corners on the distal tips of the electrodes, producing asperities on the distal end faces of the electrodes, or increasing the edge/surface area ratio of the electrode terminals. '882 Patent, col. 12:51-13:6. The Manwaring Patent does not disclose any of these configurations. Instead, it discloses a stainless steel wire or high temperature resistant tungsten wire. Manwaring Patent, col. 5:20-23. There is no discussion of creating sharp edges and corners in the wire, producing asperities on the wire, or increasing the edge/surface area ratio of the wire.

B. Claim 28: Independent method Claim 28 of the '882 Patent includes claim limitations that are not disclosed in the Manwaring Patent. It requires, among other things, that the energy delivered to the target site "ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure." The Manwaring Patent does not disclose these limitations.

First, the Manwaring Patent does not disclose the claimed ablation. The '882 Patent uses the words "ablation" and "ablate" in the context of the invention to mean the disintegration or volumetric removal of tissue. '882 Patent, col. 23:61 ("ablate (i.e., disintegrate)"); col. 10:38-54 ("the tissue structure is volumetrically removed"). Moreover, the '882 Patent repeatedly describes "cutting" and "ablation" as different, alternative forms of treatment. The Field of the Invention describes methods "to cut and ablate tissue." '882 Patent, col. 1:20-23. The Summary of the Invention describes "electrosurgical interventions, such as ablation and cutting of body structures," Id., col. 3:48-50. The Description of the Preferred Embodiment refers to target tissue that "is

selectively ablated or cut." Id., col. 8:43. Moreover, the '882 Patent distinguishes ablation of the invention from conventional vaporization of tissue. Id., col. 23:60-24:4.

Although the Manwaring Patent discloses vaporization and cutting, it does not disclose tissue ablation. The Manwaring Patent never uses the word ablation or ablate. Moreover, the Manwaring Patent never refers to volumetric removal of tissue or the disintegration of tissue. Instead, the Manwaring Patent describes vaporizing tissue in order to cut the tissue. In the Field of the Invention section, the Manwaring Patent describes "tissue dissection and coagulation," not ablation. In describing the operation of the device, the Manwaring Patent shows how the vaporization technique is used to make "cookie cuts" in the tissue. Manwaring Patent, col. 7:57-8:18 & Figs. 7A-7C. This is a very different method than Patentee's method of ablating tissue.

Second, the Manwaring Patent does not disclose a method for minimizing necrosis of tissue underlying the ablated tissue. The '882 Patent explains that, before Patentee's inventions, electrosurgical techniques for tissue ablation relied on arcing between a treating electrode and tissue; that arcing often generates very high temperatures; that these high temperatures cause unwanted necrosis of collateral tissue; and that this inability to control depth of necrosis in the prior art is a significant disadvantage. '882 Patent, col. 2:33-46.

Like the prior art, the Manwaring Patent relies on high temperatures to achieve cutting or coagulation. The Manwaring Patent explains that sparking in the region of the single monopolar electrode "results in the generation of extremely high temperatures" and that these high temperatures cause the adjacent tissue to be "rapidly desiccated and then vaporized." Manwaring Patent, col. 6:50-63; 7:19-25. The Manwaring Patent refers to the region near the electrode tip as "a high temperature region." Id., col. 6:3-18. This "extremely high temperature" approach is precisely the approach that the '882 Patent avoids.

The Office Action states at page 2-3 that the Manwaring Patent's method will not cause substantial necrosis of underlying tissue because it uses a small electrode and that the '882 Patent states at col. 9:65-10:8 that small electrode diameters are sufficient to avoid substantial tissue necrosis. Patentee respectfully submits that this reading of the '882 Patent is incorrect. The cited language actually teaches that a multiplicity of small electrodes, when used in the context of the inventions, reduces the extent of tissue necrosis. In the very same paragraph on which the Examiner relies, the '882 Patent states that using such a multiplicity of electrodes "is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the

depth of tissue necrosis may not be sufficiently limited." Id., col. 10:11-14. Clearly, the '882 Patent teaches that using a single electrode, like the Manwaring Patent, can lead to uncontrolled tissue necrosis whereas using multiple small electrodes in the context of the '882 inventions will limit collateral damage. Although the claimed invention can be practiced with a single electrode terminal, a single electrode terminal will not necessarily avoid substantial tissue necrosis as claimed in Claim 28.

- 1. Claim 29: Claim 29 depends on Claim 28. In addition to the limitations of Claim 28, Claim 29 also requires vaporizing the electrically conducting fluid over the electrode terminal and inducing the discharge of photons to the target site in contact with the vapor layer. For the same reasons that the Manwaring Patent does not anticipate Claim 1, the Manwaring Patent does not disclose the additional limitations of Claim 29. The Manwaring Patent discloses a method in which energy is discharged (sparking) followed by vaporization. Manwaring Patent, col. 6:50-63 ("RF sparking followed by fluid vaporization"). In contrast, the method of Claim 29 claims the opposite sequence, namely, creating a vapor layer followed by discharging energy to the tissue in contact with the vapor layer.
- 2. Claim 30: Claim 30 depends on Claim 28. In addition to the limitations of Claim 28, Claim 30 also requires creating a vapor layer over the electrode terminal and inducing the discharge of energetic electrons to the target site in contact with the vapor layer. For the same reasons that the Manwaring Patent does not anticipate Claim 1 or Claim 14, the Manwaring Patent does not disclose the additional limitations of Claim 30. The Manwaring Patent discloses a method in which energy is discharged (sparking) followed by vaporization. Manwaring Patent, col. 6:50-63 ("RF sparking followed by fluid vaporization"). In contrast, the method of Claim 30 claims the opposite sequence, namely, creating a vapor layer followed by discharging energy to the tissue in contact with the vapor layer. Moreover, as explained above in the context of Claim 14, the Manwaring Patent does not disclose the discharge of energetic electrons as that term is used in the '882 Patent. Nowhere does the Manwaring Patent state or suggest that the electrons have an energy level greater than or equal to 4 to 5 electron volts, as described in the '882 Patent. '882 Patent, col. 11:27-30, 12:25-27.
- 3. Claim 46: Claim 46 depends on Claim 30 which, in turn, depends on Claim 28. In addition to the limitations of Claims 28 and 30, Claim 46 also requires that the electrode terminal be "configured to promote bubble nucleation causing the formation of the vapor layer."

For the same reasons that the Manwaring Patent does not disclose Claim 30, and for the reasons that the Manwaring Patent does not disclose Claim 46 as it depends on Claim 1, the Manwaring Patent does not disclose the limitations of Claim 46. The '882 Patent describes creating sharp edges or corners in the electrode terminal, producing asperities on the electrode terminal, and increasing the edge/surface area ratio of the electrode terminal as techniques for configuring an electrode terminal to promote bubble nucleation. '882 Patent, col. 12:51-13:6. The Manwaring Patent does not describe any of these techniques.

D. The other Claims that the Examiner rejected in light of Manwaring depend on either Claim 1 or Claim 28 and, therefore, are not anticipated by the Manwaring Patent for the same reasons set forth above.

Claim Rejections Under 35 U.S.C. § 102 Based On The Slager Article

According to the Office Action, Claims 1, 13, 17, 18, 23, 24, 26, 28, 29, 31, 37, 46, 47, 48, 49, and 54 stand rejected under 35 U.S.C. § 102 based on the Slager Article. Patentee respectfully disagrees. As set forth below, the Slager Article fails to disclose each and every limitation of the claims and, as a result, cannot anticipate.

Claim 1: Claim 1 is an independent method claim. Claim 1, and all the claims that depend thereon, require that energy be applied "to a target site on a patient body structure." Claim 1 and its dependent claims also require that the electrode terminal be positioned in close proximity to the target site "in the presence of an electrically conducting fluid" and that, when a high frequency voltage is applied, the electrically conducting fluid be vaporized in a thin layer over the electrode terminal. The Slager Article does not anticipate Claim 1 or its dependent claims because it does not disclose these limitations. As set forth below, the Slager Article performed its method in vitro (not in vivo) on dead tissue taken from cadavers at autopsy, not on target sites on patient body structures. Moreover, the Slager Article nowhere states or suggests that electrically conducting fluid is vaporized, but instead discloses that the fluid inside the tissue itself is vaporized.

Claim 1 expressly requires that the method be performed on a target site on a patient body structure. The phrase "target site on a patient body structure" plainly requires a living animal, not a cadaver. This meaning is confirmed in the '882 Patent specification, which makes clear that the inventions are for use in treating living patients, not cadavers. In the Summary of the Invention section, for example, the '882 Patent describes that the inventive methods allow "the surgical team to perform electrosurgical interventions" and are "useful for surgical procedures." '882 Patent, col. 3:45-64. The Description of the Preferred Embodiment section similarly refers to "the treating physician" and to "the surgical team." Id., col. 8:3-7, col. 23:64-24:2. These descriptions make clear that the inventions cover the treatment of living patients, not in vitro tests on cadavers.

Although the "target site on a patient body structure" language first appears in Claim 1's preamble, the language plainly is a claim limitation. The phrase "the target site" appears in the body of Claim 1 and, by its use of the word "the," finds its antecedent basis in the preamble language. Moreover, claims that depend on Claim 1, such as Claim 54 and Claim 55, use the phrase "the target site" and "the patient's body," both of which find their antecedent basis in the preamble of Claim 1. Thus, the language in the preamble qualifies as a claim limitation, not merely a statement of intended purpose. NTP, Inc. v. Research In Motion, Ltd., 392 F.3d 1336, 1359 (Fed. Cir. 2004) ("Because these limitations of claim 1 of the '960 patent derive their antecedent basis from the claim 1 preamble and are necessary to provide context for the claim limitations, the use of these limitations in the preamble limits the claim."); Eaton Corp. v. Rockwell Intern. Corp., 323 F.3d 1332, 1339 (Fed. Cir. 2003) ("When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed

The tests on which the Examiner relies in the Slager Article do not meet the "target site on a patient body structure" limitation. The aortic tissue segments that were vaporized were "autopsy specimens," also called "autopsy material." Slager Article at 1382. In other words, the tissue was dead tissue that came from human beings after they had died. Moreover, the tests were performed in vitro, which means they were performed on dead tissue outside a patient's body, not in vivo. During the Patentee's trial against Smith & Nephew involving the '882 Patent, Smith & Nephew's expert, Dr. Kenneth Taylor, made clear that the Slager Article did not meet the "patient body structure" limitation. He acknowledged under oath that the in vitro tests described in the Slager Article were performed "outside a patient's body," that they were not performed "in a living human patient," that the tissue "wasn't on the patient's body when the energy was applied," that there "wasn't any application of energy to a patient," and that "energy wasn't being applied to a patient." Exh. A (Trial Tr. at 1414:8-1415:4, 1426:20-1428:17). At most, the tissue came from a "former patient body structure" or a "deceased patient body structure," but not from a patient body structure.

The Slager Article also does not anticipate Claim 1 because it does not disclose the vaporization of electrically conducting fluid over the electrode terminal. Figure 4 of the Slager Article depicts the Slager method. It shows an "electrode," "tissue," "sparks," and "steam." Figure 4 does not describe saline or any other electrically conducting fluid being present. Moreover, the Slager Article makes clear that the source of the "steam" is the tissue being vaporized, not isotonic saline. The Slager Article specifically describes how the electrode terminal is "isolated from the tissue by the self-produced steam layer." Slager Article at 1384. The Slager Article never suggests that the source of the steam was saline. Rather, the Slager Article explains that the self-produced steam layer comes from exploding tissue cells, i.e., the cellular fluid boils and causes the cells to rupture. Id. at 1385 ("We suppose that in biological tissue, both heating factors lead to such a rapid conversion of water into steam that cells 'explode' and nonwater-containing tissue parts are fractioned into many small particles.").

To be sure, the Slager Article states that the in vitro tissue samples were "immersed" in saline solution. Slager Article at 1383. But this does not necessarily mean that the electrode terminal was in the presence of saline when energy was applied to the tissue. As dictionaries make clear, the word "immersed" does not necessarily mean that the Slager tissue samples were covered by saline. Rather, the samples merely could have been surrounded by saline. Exh. B (MerriamWebster's Collegiate Dictionary at 579 (10th ed. 1993) (defining "immerse" as "to plunge into something that surrounds or covers; esp: to plunge or dip into a fluid")). Under the plain meaning of "immersed," the tissue samples in the Slager Article may have been placed into a dish with saline, and may have been surrounded by saline, but the surface of the tissue may not have been covered by saline. This appears to be exactly what the Slager Article describes, because Figure 4, which shows the electrode in operation on the upper surface of a tissue specimen, never shows saline covering the tissue.

- 1. Claim 13: Claim 13 depends on Claim 1. In addition to the limitations of Claim 1, Claim 13 also requires that a portion of the induced energy be "in the form of photons having a wavelength in the ultraviolet spectrum." The Slager Article does not disclose the emission of ultraviolet photons. First, the Slager Article merely refers to the generation of sparks. It does not say that those sparks include ultraviolet light. Second, as the declaration of Kenneth Stalder demonstrates, sparks in isotonic saline do not inherently emit ultraviolet photons. Indeed, Dr. Stalder's experiments show that even at the voltage mentioned in the Slager Article - 1200 volts peak to peak - ultraviolet photons are not inherently emitted. Finally, the Slager Article does not disclose sparking in isotonic saline or any other electrically conducting fluid. According to the text of the Slager Article, the vaporized region is "self-produced," that is, it develops from the vaporization of the fluid inside the tissue cells.
- 2. Claim 37: Claim 37 depends on Claim 1. In addition to the limitations of Claim 1, Claim 37 requires that the electrode terminal be surrounded and supported by an insulating matrix that comprises "an inorganic material." The Slager Article does not disclose this limitation. The device on which the Examiner relies to meet the limitations of Claim 1 and Claim 37 is depicted in Figure 1. This electrode does not include an inorganic insulating matrix. Rather, it discloses the use of an organic insulating material - Teflon - to cover a portion of the stainless steel electrode. Slager Article at 1383. Teflon is a well-known organic polymer; it is not inorganic.
- Claim 46: Claim 46 depends on Claim 1. In addition to the limitations of Claim 1, Claim 46 also requires that the electrode terminal be "configured to promote bubble nucleation causing the formation of the vapor layer." The Slager Article does not disclose these additional limitations. The '882 Patent explains that electrode terminals can be configured to promote bubble nucleation by, for example, producing sharp edges and corners on the distal tips of the electrodes, producing asperities on the distal end faces of the electrodes, or increasing the

edge/surface area ratio of the electrode terminals. '882 Patent, col. 12:51-13:6. The Slager Article does not disclose any of these configurations. Instead, it merely depicts in cross-section a stainless steel electrode (Figure 1), but there is no discussion of creating sharp edges and corners in the electrode, producing asperities on the electrode, or increasing the edge/surface area ratio of the electrode.

4. Claim 54: Claim 54 depends from Claim 1. In addition to the limitations of Claim 1, Claim 54 also requires that the method include "evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal." The Slager Article does not disclose this limitation. The Slager Article merely describes removing bubbles as an area for further study. Slager Article at 1386. The Slager Article does not describe a method or apparatus for evacuating the bubbles. The Slager Article never depicts or explains what device will be used to perform the suction. The electrode depicted in Figures 1 and 4 is shown without a suction lumen adjacent the electrode and there is no discussion about how to configure the electrode terminal with a suction lumen. Moreover, the Slager Article never states or suggests that a suction lumen "adjacent the electrode terminal" should be used. As Smith & Nephew's expert at trial, Dr. Kenneth Taylor, admitted in his testimony during trial, the Slager Article does not describe suction of fluid through a lumen adjacent the electrode. Exh. A (Trial Tr. at 1424:3-1426:6).

Claim 26: Claim 26 is an independent method claim. Claim 26, and all the claims that depend thereon, require that energy be applied "to a target site on a patient body structure." Claim 26 and its dependent claims also require that the electrode terminal be positioned in close proximity to the target site "in the presence of an electrically conducting fluid." For the same reasons as set forth above with respect to Claim 1, the Slager Article does not disclose these limitations. The Slager Article's method was performed in vitro on dead tissue samples from a cadaver, not on a "patient body structure." Moreover, the Slager Article does not disclose or suggest that the electrode is positioned in the presence of an electrically conducting fluid. To the contrary, the Slager Article suggests that saline is not present, because it is not shown in Figure 4 and because the Slager Article describes the vaporization of cellular fluid in the tissue, not of saline covering the tissue specimens.

Claim 28: Claim 28 is an independent method claim. Claim 28, and all the claims that depend thereon, require that energy be applied "to a target site on a patient body structure." Claim 28 and its dependent claims also require that the electrode terminal be positioned in close proximity to the target site "in the presence of an electrically conducting fluid." Finally, Claim 28 requires that the method "ablate" the patient body structure.

For the same reasons as set forth above with respect to Claim 1, the Slager Article does not disclose the "patient body structure" or electrode terminal "in the presence of electrically conducting fluid" limitations. The Slager Article's method was performed in vitro on dead tissue samples from a cadaver, not on a "patient body structure." Moreover, the Slager Article does not disclose or suggest that the electrode is positioned in the presence of an electrically conducting fluid. To the contrary, the Slager Article suggests that saline is not present, because it is not shown with the electrode in Figure 4 and because the Slager Article describes the vaporization of cellular fluid in the tissue, not the vaporization of saline covering the tissue specimens.

The Slager Article also does not disclose ablation. The '882 Patent uses the words "ablation" and "ablate" in the context of the invention to mean the disintegration or volumetric removal of tissue. '882 Patent, col. 23:61 ("ablate (i.e., disintegrate)"); col. 10:38-54 ("the tissue structure is volumetrically removed"). Moreover, the '882 Patent distinguishes ablation of the invention from conventional vaporization of tissue. '882 Patent, col. 23:60-24:4. The Slager Article does not disclose ablation, but merely discloses conventional vaporization of tissue.

- 1. Claim 29: Claim 29 depends on Claim 28. In addition to the limitations of Claim 28, Claim 29 also requires vaporizing the electrically conducting fluid over the electrode terminal and inducing the discharge of photons to the target site in contact with the vapor layer. For the same reasons that the Slager Article does not anticipate Claim 1, the Slager Article does not disclose the additional limitations of Claim 29. The Slager Article does not disclose the vaporization of electrically conducting fluid. Instead, it discloses a "self-produced" steam layer in which the fluid inside the tissue cells is vaporized.
- 2. Claim 37: Claim 37 depends on Claim 28. In addition to the limitations of Claim 28, Claim 37 requires that the electrode terminal be surrounded and supported by an insulating matrix that comprises "an inorganic material." The Slager Article does not disclose this limitation. The device on which the Examiner relies to meet the limitations of Claim 28 and Claim 37 is depicted in Figure 1. This electrode does not include an inorganic insulating matrix. Rather, it discloses the use of an organic insulating material — Teflon — to cover a portion of the stainless steel electrode. Slager Article at 1383.

- Claim 46: Claim 46 depends on Claim 28. In addition to the limitations of Claim 28, Claim 46 also requires that the electrode terminal be "configured to promote bubble nucleation causing the formation of the vapor layer." The Slager Article does not disclose these additional limitations. The '882 Patent explains that electrode terminals can be configured to promote bubble nucleation by, for example, producing sharp edges and corners on the distal tips of the electrodes, producing asperities on the distal end faces of the electrodes, or increasing the edge/surface area ratio of the electrode terminals. '882 Patent, col. 12:51-13:6. The Slager Article does not disclose any of these configurations. Instead, it merely depicts in cross-section a stainless steel electrode (Figure 1), but there is no discussion of creating sharp edges and corners in the electrode, producing asperities on the electrode, or increasing the edge/surface area ratio of the electrode.
- Claim 54: Claim 54 depends on Claim 28. In addition to the limitations of Claim 28, Claim 54 also requires that the method include "evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal." The Slager Article does not disclose this limitation. The Slager Article merely describes removing bubbles as an area for further study. Slager Article at 1386. The Slager Article does not describe a method or apparatus for evacuating the bubbles. The Slager Article never depicts or explains what device will be used to perform the suction. The electrode depicted in Figures 1 and 4 is shown without a suction lumen adjacent the electrode and there is no discussion about how to configure the electrode terminal with a suction lumen. Moreover, the Slager Article never states or suggests that a suction lumen should be positioned "adjacent the electrode terminal." As Smith & Nephew's expert at trial, Dr. Kenneth Taylor, admitted in his trial testimony, the Slager Article does not describe fluid evacuation through a suction lumen adjacent the electrode. Exh. A (Trial Tr. at 1424:3-1426:6).

35 U.S.C. § 103

Claim Rejections Under 35 U.S.C. § 103 Based On The Rydell Patent

According to the Office Action, Claims 28, 37, 38, 52, 53, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,007,908 to Rydell (hereinafter referred to as "the Rydell Patent").2 Page 4 of the Office Action provides:

> Rydell discloses a method of applying high frequency voltage between an electrode terminal and return electrode in the presence of saline to ablate a turnor [e.g., polyps] on a patient's body (1:28-33, 3:21-56). The use of saline to wash the treatment site inherently cools the tissue adjacent the target site because the high temperatures of electrosurgical cutting and coagulation results in the saline having a cooling effect. In cutting, the electrode movement would inherently allow the saline to contact the tissue after the tissue had been subjected to the cutting or coagulating electric field. Rydell does not disclose that the method is used without causing substantial tissue necrosis below the surface of the body structure ablated. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Rydell in a method of electrosurgery without causing substantial tissue necrosis below the surface of the body structure ablated in order to ablate tissue [polyps] in the gastrointestinal track. The skilled artisan would find obvious the step of preventing substantial tissue necrosis in order to increase patient's successful outcome after the surgery.

Patentee disagrees. The Rydell Patent cannot render the claimed inventions obvious because the Office Action fails to establish a proper prima facie case of obviousness for any of the rejections. Moreover, there is significant objective evidence that independent Claim 28, and therefore all the claims that depend thereon, would not have been obvious, as set forth in the accompanying declaration under 37 C.F.R. 1.68.

The Office Action Fails To Establish A Prima Facie Case

An Office Action must establish a prima facie case of obviousness in order to reject claims under 35 U.S.C. § 103. To establish a prima facie case of obviousness, at least three basic criteria must be met: 1) there must be some suggestion or motivation, either in the reference itself or in the

² Dependent claims 37, 38, 52, 53, and 55 alternatively depend on Claim 1. Because the Office Action does not reject Claim 1 based on the Rydell Patent, Patentee understands that the Office Action rejects these dependent claims only to the extent they depend on Claim 28.

knowledge generally available to one of ordinary skill in the art, to modify the reference; 2) there must be a reasonable expectation of success; and 3) the prior art reference must teach or suggest all the claim limitations. MPEP § 2143.

1. Claim 28: Independent Claim 28, and all of the claims that depend thereon, require that the high frequency voltage be "sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure." The Rydell Patent does not disclose or suggest these limitations, because the Rydell Patent merely discloses conventional arcing to cut tissue.

The '882 Patent uses the words "ablation" and "ablate" in the context of the invention to mean the disintegration or volumetric removal of tissue. '882 Patent, col. 23:61 ("ablate (i.e., disintegrate)"); col. 10:38-54 ("the tissue structure is volumetrically removed"). Moreover, the '882 Patent distinguishes between ablation, on the one hand, and cutting, on the other. The Field of the Invention describes methods "to cut and ablate tissue." '882 Patent, col. 1:20-23. The Summary of the Invention describes "electrosurgical interventions, such as ablation and cutting of body structures." Id., col. 3:48-50. The Description of the Preferred Embodiment refers to target tissue that "is selectively ablated or cut." Id., col. 8:43. Moreover, the '882 Patent distinguishes ablation of the invention from conventional vaporization of tissue. Id., col. 23:60-24:4.

Although the Rydell Patent discloses tissue cutting, it does not disclose tissue ablation. The Rydell Patent never uses the word ablation or ablate. Moreover, the Rydell Patent never refers to volumetric removal of tissue or the disintegration of tissue. Instead, the Rydell Patent describes cutting or severing tissue. In the Summary of the Invention section, the Rydell Patent states that the electrodes of the invention are brought into contact with the "tissue to be severed." Col. 1:63-2:2. Similarly, in the Description of the Preferred Embodiment, the Rydell Patent describes the use of an "arc" that causes "tissue to be severed." Col. 3:49-53. Severing tissue is different from ablating tissue as that term is used in the '882 Patent.

The Rydell Patent also does not disclose a method for avoiding substantial tissue necrosis under the ablated tissue, as Claim 28 requires. The '882 Patent explains that, before Patentee's inventions, electrosurgical techniques for tissue ablation relied on arcing between a treating electrode and tissue; that arcing often generates very high temperatures; that these high temperatures cause unwanted necrosis of collateral tissue; and that this inability to control depth of necrosis in the prior art is a significant disadvantage. '882 Patent, col. 2:33-46. Like the prior art,

the Rydell Patent relies on arcing to achieve cutting or coagulation. The Rydell Patent explains that, to cut tissue, "an arc is created between the active electrode and tissue" and "the arc caus[es] the tissue to be severed." Rydell Patent, col. 3:49-53. This "arcing" approach is precisely the approach that the '882 Patent avoids on the grounds that "arcing" results in substantial tissue necrosis.

The Office Action acknowledges that the Rydell Patent does not disclose a method that avoids substantial tissue necrosis below the surface of the ablated body structure. Nonetheless. without citing any authority, the Office Action concludes that the skilled artisan would find the step of preventing such necrosis obvious "in order to increase patient's successful outcome after the surgery." Patentee submits that the Office Action does not make out a prima facie case of obviousness. There is no teaching or suggestion in the Rydell Patent to avoid arcing, which is a cause of substantial tissue necrosis. Instead, the Rydell Patent affirmatively relies on such arcing. The Office Action provides no evidence which suggests that it would have been obvious or desirable to modify the Rydell technique in order to avoid arcing or that the Rydell instrument would work without arcing. Because arcing is the mechanism relied on by Rydell to achieve cutting, and because arcing leads to substantial tissue necrosis, the Rydell Patent neither teaches nor suggests how to ablate tissue without causing substantial tissue necrosis.

2. Claim 53: Claim 53 depends on Claim 52, which in turn depends on Claim 28. In addition to the limitations of Claim 28 and Claim 52, Claim 53 also requires that the method include the step of translating the electrode terminal "to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field." At page 4 of the Office Action, the Examiner states that electrode movement "inherently" would allow the saline to contact tissue after the tissue had been subjected to the electric field. Patentee respectfully disagrees.

Nowhere does the Rydell Patent disclose or suggest this limitation. The Rydell Patent discloses the optional use of saline, in unspecified amounts, to wash the surgical site to "facilitat[e] the viewing through the endoscope of the surgical field." Rydell Patent, col. 3:53-57. The Rydell Patent never discloses or suggests that the saline contacts the tissue after the tissue has been subjected to the electric field, as Claim 53 requires. Indeed, there is nothing in the Rydell Patent which suggests that any saline remains in the surgical field after the electrosurgical arc cuts the tissue. The Rydell Patent does not disclose the quantity or rate of saline application and, as a result, the saline may well be gone after energy is applied. Moreover, the Rydell method is designed for

use in the gastrointestinal track. <u>Id.</u>, col. 1:9-12. Unlike fluid-holding spaces in the body (such as the shoulder or knee), the gastrointestinal track will not "hold" fluid at the surgical site. Because the saline described in the Rydell Patent is free to flow away from the surgical site, and because the Rydell Patent does not describe a way (much less a need) to maintain the saline near the surgical site, saline contact with tissue after the application of energy is simply not inherent.

B. Objective Evidence Of Nonobviousness

Additionally, there is significant objective evidence that Claim 28 would not have been obvious under 35 U.S.C. § 103, as set forth in the accompanying declaration of Michael Baker under 37 C.F.R. 1.68.

Claim Rejections Under 35 U.S.C. § 103 Based On The Manwaring Patent Or The Slager Article.

According to the Office Action, Claims 21 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Manwaring Patent or the Slager Article. Page 5 of the Office Action provides:

> Manwaring or Slager disclose the claimed invention except for the claimed distances between the proximal electrode terminal portion and the distal return electrode portion of 0.5-10 mm and fluid exposed electrical terminal portion being 0-2.0 mm. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Manwaring or Slager to the claimed dimensions because these dimensions have not been disclosed for a particular purpose or to solve a stated problem and it appears that one of ordinary skill in the art would use these dimensions as a design choice. Applicant has not established any criticality to these dimensions.

Patentee disagrees. An Office Action must establish a prima facie case of obviousness in order to reject claims under 35 U.S.C. § 103. To establish a prima facie case of obviousness, at least three basic criteria must be met: 1) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; 2) there must be a reasonable expectation of success; and 3) the prior art reference must teach or suggest all the claim limitations. MPEP § 2143. Neither the Manwaring Patent nor the Slager Article renders Claims 21 and 25 obvious, because the Office Action fails to establish a prima facie case of obviousness for either of the rejections. Additionally, there is significant objective evidence that Claim 1 of the '882 Patent, on which Claims 21 and 25 depend, would not have been obvious under 35 U.S.C. § 103, as set forth in the accompanying declaration under 37 C.F.R. 1.68.

A. The Office Action Fails To Establish A Prima Facie Case

Claims 21 and 25 depend on Claim 1. In addition to the limitations of Claim 1, Claim 21 requires that the most proximal portion of the electrode terminal be 0.5 to 10 mm from the most distal portion of the return electrode. Claim 25 requires that the exposed portion of the electrode terminal be 0.0 to 2.0 mm. The Office Action acknowledges that neither the Manwaring Patent nor the Slager Article discloses the claimed distances and dimensions. Nonetheless, the Office Action contends that it would have been obvious to modify Manwaring and Slager because the claimed distances and dimensions "have not been disclosed for a particular purpose or to solve a stated

problem" and because "[a]pplicant has not established any criticality to these dimensions." Patentee respectfully disagrees.

The '882 Patent specification describes a particular purpose for each of these dimensions. With respect to Claim 21, the inventors conceived of using a distance of 0.5 to 10 mm between the electrode terminal and the return electrode to "reduce[] the risk of current shorting" between the electrodes. '882 Patent, col. 19:43-45. With respect to Claim 25, the '882 Patent explains that the length of the electrode terminal exposed to the electrically conducting fluid is selected "to minimize the depth of ablation" and to promote high current densities. Id., col. 5:47-57; col. 22:2-6.

Neither the Manwaring Patent nor the Slager Article teaches or suggests either of these limitations. First, shorting between the electrode terminal and the return electrode is not an issue in Manwaring or in Slager. The Manwaring Patent describes a conventional monopolar system, in which the return electrode is affixed to the outside of the patient's body. Manwaring Patent, col. 2:66; Exh. A (Trial Tr. at 899-900 (Manwaring) and 1314 (Taylor)). Because the return electrode is remote from the surgical site, there is no risk of shorting between the electrodes in Manwaring and, therefore, no suggestion or motivation to address the distance between them. In the Slager Article, there also is no suggestion that shorting between the electrodes was a consideration or an issue. Second, neither Manwaring nor Slager discusses the relationship between the length of the exposed electrode and the depth of ablation. To begin with, neither reference discusses ablation at all, much less in relation to electrode terminal extension. While the Slager Article discusses the extent of necrosis in the vaporized regions, the Slager Article never ties the depth of necrosis to the length of the exposed electrode. Similarly, while the Manwaring Patent briefly discusses the desire to control the location of the high temperature zone created in the vicinity of the electrode terminal, there is no discussion in the Manwaring Patent about the relationship between the length of the exposed electrode and tissue ablation.

Objective Evidence Of Nonobviousness

Additionally, there is significant objective evidence that Claim 1 of the '882 Patent, on which Claims 21 and 25 depend, would not have been obvious under 35 U.S.C. § 103, as set forth in the accompanying declaration of Michael Baker under 37 C.F.R. 1.68.

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Claim Rejections Under 35 U.S.C. § 103 Based On The Slager Article In View Of Schneiderman.

Document 35-2

According to the Office Action, Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Slager Article as applied to Claim 26 and in further view of U.S. Patent No. 4.092.986 to Schneiderman (hereinafter referred to as "the Schneiderman Patent"). Page 5 of the Office Action states:

> Slager discloses the claimed invention except for using 700-900 volts peak to peak in the electrosurgical method. Schneiderman teaches the use of 700-900 volts peak to peak in the electrosurgical method (figs. 5 and 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Schneiderman in the method of Slager because the use of approximately 450-900 volts peak to peak was common knowledge in the art for electrosurgical devices as seen in the instrumentation capabilities shown in figs. 5 and 6. Applicant has not established any criticality of operating in the range of 700-900 volts peak to peak.

Patentee disagrees. Neither Slager nor Schneiderman discloses each of the limitations of Claim 27 and, as a result, the Office Action fails to present a prima facie case of obviousness. Moreover, there is objective evidence that Claim 27 would not have been obviousness to one of ordinary skill.

A. The Office Action Fails To Establish A Prima Facie Case

It is well established that an Office Action must establish a prima facie case of obviousness in order to reject claims under 35 U.S.C. § 103. This requires, at a minimum, that: (1) the prior art references, when combined, must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation in the references or in the knowledge of a person of ordinary skill in the art to modify the references or combine their teachings; and (3) there must be a reasonable expectation that the combination would be successful. MPEP § 2143.

Claim 27 depends on Claim 26. In addition to the limitations of Claim 26, Claim 27 also requires that the high frequency voltage applied between the electrode terminal and the return electrode be in the range of 700 to 900 volts peak to peak.

Here, the Slager Article and the Schneiderman Patent do not teach or suggest all of the claim limitations.

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First, for the reasons set forth above, the Slager Article does not disclose "applying energy to a target site on a patient body structure," as Claim 26 requires, because the Slager Article applies energy in vitro to dead tissue samples obtained from cadavers at autopsy.

Second, for the reasons set forth above, the Slager Article does not disclose positioning the electrode terminal "in the presence of an electrically conducting fluid," as Claim 26 requires, but instead discloses a "self-produced" steam layer that results from the vaporization of the fluid in the tissue cells.

Finally, there is no suggestion or motivation to combine the teachings of the Slager Article with the Schneiderman Patent and apply a voltage in the range of 700 to 900 volts peak to peak. The Slager Article discloses a voltage of 1200 volts peak to peak. The Slager Article states that it seeks to generate "extremely high current density" at the electrode tip. Slager Article at 1385. Nothing in the Slager Article suggests that the apparatus would work at the significantly lower claimed voltages of between 700 to 900 volts peak to peak. Moreover, the Schneiderman Patent does not teach or suggest that it would be desirable to use a voltage in the range of 700 to 900 volts peak to peak. Rather, the Schneiderman Patent's electrosurgical unit is designed for lower voltage procedures. The Schneiderman Patent explains that "the vast majority of dental surgical procedures is conducted at intensities of between 450 and 600 V p-p." Schneiderman Patent, col. 7:35-37. Because Schneiderman describes the desirability of using voltages lower than those claimed in Claim 27, and because Slager describes the desirability of using voltages higher than those claimed in Claim 27, one of ordinary skill would not have been motivated to combine the two references.

Objective Evidence Of Nonobviousness

Additionally, there is significant objective evidence that Claim 26, on which Claim 27 depends, would not have been obvious under 35 U.S.C. § 103, as set forth in the accompanying declaration of Michael Baker under 37 C.F.R. 1.68.

Claim Rejections Under 35 U.S.C. § 103 Based On Slager Or Rydell In View Of Morrison.

According to the Office Action, Claims 39 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Slager Article or the Rydell Patent as applied to claim 37, and further in view of U.S. Patent No. 3,970,088 to Morrison (hereinafter referred to as "the Morrison Patent"). Page 6 of the Office Action states:

> Slager or Rydell disclose the claimed invention except for a terminal electrode that is recessed or flush with surrounding insulative matrix. Morrisson teaches a terminal electrode that is recessed or flush with surrounding insulative matrix (figs. 6-12, 14, 21, 22, 38 and 39; 8:5-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Morrisson in the method of Slager or Rydell in order to have the return electrode contact tissue before the active electrode so as to have an arc develop at the electrode terminal or to surround the electrode terminal to expose only a small portion to facilitate arcing.

Patentee disagrees. Neither Slager nor Rydell nor Morrison, either alone or in combination, discloses each of the limitations of Claims 39 and 40 and, as a result, the Office Action fails to present a prima facie case of obviousness. Moreover, there is objective evidence that Claims 1 and 28 and 37, on which Claims 39 and 40 depend, would not have been obviousness to one of ordinary skill, as set forth in the accompanying declaration of Michael Baker under 37 C.F.R. 1.68.

The Office Action Fails To Establish A Prima Facie Case

It is well established that an Office Action must establish a prima facie case of obviousness in order to reject claims under 35 U.S.C. § 103. This requires, at a minimum, that: (1) the prior art references, when combined, must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation in the references or in the knowledge of a person of ordinary skill in the art to modify the references or combine their teachings; and (3) there must be a reasonable expectation that the combination would be successful. MPEP § 2143.

Claims 39 and 40 depend on Claim 37, which in turn depend on Claims 1 or 28. In addition to the limitations of Claims 1 or 28 and 37, Claim 39 requires that the distal surface of the electrode terminal be recessed below the surface of the inorganic insulating matrix, and Claim 40 requires that the electrode terminal be flush with the surface of the inorganic insulating matrix. Here, the combination of Slager or Rydell with Morrison does not render either Claim 39 or Claim 40 obvious.

The Office Action recognizes that neither Slager nor Rydell discloses an electrode terminal that is recessed below or flush with an inorganic insulating matrix, but asserts that Figures 6-12, 14, 21, 22, 38, and 39 of the Morrison Patent do. Patentee respectfully disagrees. An examination of each cited figure in the Morrison Patent shows that the electrode terminal (element 20 or element 50) extends beyond the insulation (element 18 or 52). The cited figures of Morrison neither teach nor suggest recessing the electrode terminal or making it flush.

In addition, even if the Morrison Patent taught or suggested using a recessed or flush electrode terminal, which it does not, there is no suggestion or motivation to combine the Morrison Patent with Rydell or Slager. For the Rydell device to work, both the active electrode and the electrode terminal must be in contact with tissue. The Rydell Patent makes clear that, in order to work, an electric arc is created when the active and return electrodes "are brought into contact with tissue to be cut." Rydell Patent, col. 3:49-53; col. 1:63-2:2. If the electrode terminal in the Rydell Patent were flush or recessed, thereby making tissue contact difficult or impossible, the Rydell device would not work to cut as designed. Similarly, the electrode terminal in Slager is fully exposed to the tissue. The electrode extends beyond the Teflon insulation. Nothing in the Slager Article suggests that the device would work if the electrode were recessed below, or flush with, the Teflon insulation.

Further, Slager does not disclose the limitations of dependent Claim 37, because Slager does not disclose the use of an inorganic insulating matrix. Instead, the Slager Article describes the use of Teflon, which is an organic polymer.

Finally, neither Slager nor Rydell disclose the limitations of the independent claims on which Claims 39 and 40 depend. The Rydell Patent does not disclose the formation of a vapor layer (claim 1) or ablation without substantial tissue necrosis (claim 28). The Slager Article does not disclose positioning the electrode terminal in the presence of an electrically conducting fluid (claims 1 and 28), the vaporization of that electrically conducting fluid over the electrode terminal (claim 1), or the ablation of tissue.

Objective Evidence Of Nonobviousness B.

Additionally, there is significant objective evidence that Claims 1 and 28 and 37, on which Claims 39 and 40 depend, would not have been obvious under 35 U.S.C. § 103, as set forth in the accompanying declaration of Michael Baker under 37 C.F.R. 1.68.

CLOSING COMMENTS

Based on the foregoing, Patentee requests reconsideration and withdrawal of the rejections raised in the Office Action and that a certificate of reexamination be issued allowing and or confirming the patentability of all claims of the '882 Patent. Should the Examiner have any questions regarding this response, he is urged to telephone the undersigned at the below listed number.

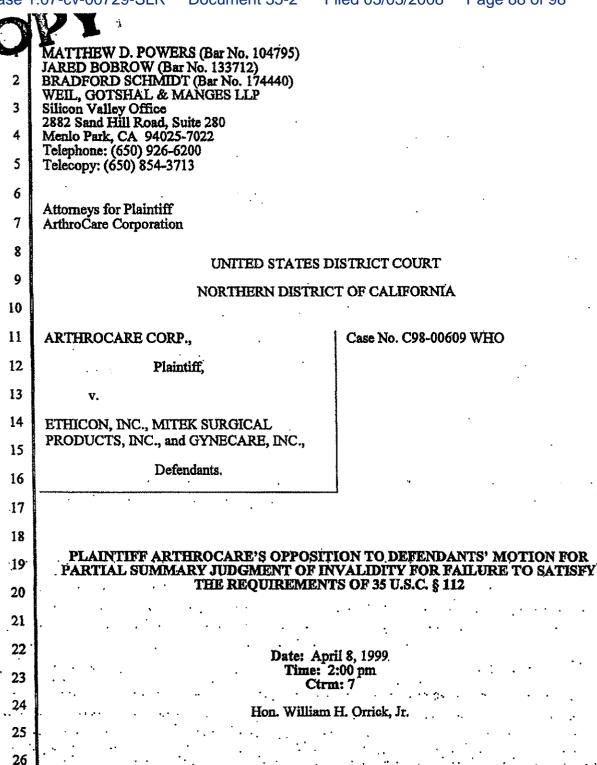
Respectfully submitted,

Richard R. Batt Reg. No. 43,485

ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, California 94085-3523 (408) 736-0224

EXHIBIT 21

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PL'S OPP'N TO DEFS' MOT, FOR PARTIAL SJ OF INVAL FOR FAILURE TO SATISFY REQ. OF 35 U.S.C. § 112

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Plaintiff ArthroCare Corporation ("ArthroCare") submits this opposition to the motion for partial summary judgment by defendants Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. (collectively "defendants") of invalidity for failure to satisfy the written description requirement of 35 U.S.C. § 112.

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INTRODUCTION

In their motion, defendants contend that they are entitled to judgment as a matter of law that ArthroCare failed to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1 for claims 40 and 44 of United States Patent No. 5,697,909 ("the '909 patent"), claim 45 of United States Patent No. 5,697,536 ("the '536 patent"), and claim 101 of United States Patent No. 5,697,281 ("the '281 patent") on the grounds that the patent specifications allegedly do not describe a single electrode embodiment of the claimed inventions. Defendants request that the Court, not a jury, resolve this issue of fact, for which defendants have the burden of proof by clear and convincing evidence, on a record with abundant evidence from renowned experts that the patent specifications describe a single electrode embodiment of the claimed inventions.

Based on the Court's previous ruling on ArthroCare's preliminary injunction motion that the patent specifications provide an adequate written description of a single electrode embodiment, defendants' motion is baseless and must be rejected. Indeed, the Court's ruling and the evidence demonstrate that ArthroCare is entitled to judgment as a matter of law that defendants cannot prevail on their written description defense. In their motion, defendants rely on expert reports from Dr. John R. LaCourse and Dr. Robert D. Tucker in arguing that the specifications do not describe a single electrode embodiment. In opposition to ArthroCare's

In order to reduce and focus the issues for trial, ArthroCare has decided to withdraw its allegations that defendants infringe claim 1 (and claims 17-18, 21, 23-24 that depend thereon and multiple dependent claims 37, 38, 46, 47 when read to depend on claim 1) and claim 32 (and claim 33 that depends thereon) of United States Patent No. 5,697,882 ("the '882 patent") from this lawsuit. In addition, ArthroCare will not bring suit against defendants for infringement of these claims based on their current or prior methods. As a result, the portions of defendants' motion that concern these claims are most and may not be decided by the Court. Indeed, the Court lacks subject matter jurisdiction to reach any issues concerning these claims, because there is no longer even declaratory judgment jurisdiction over these claims. See Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1059 (Fed. Cir. 1995); Grain Processing Corp. v. American Maize-Prods. Co., 840 F.2d 902, 905-06 (Fed. Cir. 1988).

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motion for preliminary injunction, defendants presented the same opinions and arguments, both by declaration and written testimony, from the same experts in support of the same argument lack of written description of a single electrode embodiment. The Court determined, as part of its ruling on ArthroCare's preliminary injunction motion, that ArthroCare met the written description requirement for claims 40 and 44 of the '909 patent, claim 45 of the '536 patent, and claim 101 of the '281 patent. The Court made that determination in the context of a motion on which ArthroCare bore the burden of proof on the issue of invalidity. However, to prevail at trial, defendants bear the burden of proving their written description defense by "clear and convincing evidence." Thus, as ArthroCare demonstrated in its motion filed on March 5, 1999, ArthroCare not defendants — is entitled to partial summary judgment that the patent specifications meet the written description requirement of § 112, ¶ 1 for single electrode embodiments.

At the very least, the Court should deny defendants' motion for partial summary judgment because ArthroCare has raised genuine issues of material fact.² Dr. Leslie A. Geddes, who is a world-renowned expert in the field of electrosurgery, author of 754 publications, and named inventor on 23 issued patents, flatly refutes defendants' contention that the patent specifications do not describe a single electrode embodiment. Dr. Geddes rendered his opinion after a thorough review of the '909, '536, and '281 patents, the evidence and opinions presented by defendants, including declarations, reports, and declarations of Drs. LaCourse and Tucker, the Court's claim construction, and the prior art. Dr. Geddes' opinions are supported by the views of electrical engineer and inventor of electrosurgical devices, Mr. James Doss, who submitted a declaration in connection with ArthroCare's preliminary injunction motion. Further, the testimony of Philip E. Eggers and Hira V. Thapliyal, co-inventors of the patents-in-suit, confirm Dr. Geddes' opinion that the patent specifications describe a single electrode embodiment of the claimed inventions.

Because there are disputes between the parties' experts on the written description issue, ArthroCare, at minimum, is entitled to have a jury consider and resolve the issue.

ArthroCare believes, however, that there are no genuine issues of material fact because the evidence clearly establishes that the specifications of the '909 patent, the '536 patent, and the' '281 patent describe a single electrode embodiment of the claimed inventions.

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ARGUMENT

II.

A. Defendants Cannot Satisfy The Requirements For Summary Judgment

Defendants are not entitled to summary judgment unless they can establish that there are no genuine issues of material fact and that they are entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The initial burden is on defendants, as the moving party, to demonstrate the absence of any genuine issue of material fact. See Celotex, 477 U.S. at 323. The Court must resolve any doubt as to the existence of a genuine issue of fact against defendants as the moving parties. See Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970).

Whether a patent applicant has complied with the written description requirement under § 112, ¶ 1 is a question of fact. See Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998). To satisfy the written description requirement, the patent specification need not explicitly describe each embodiment encompassed by a claim, but "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." Id. (quoting In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989)) (internal quotes omitted). Defendants must establish invalidity by clear and convincing evidence. See Rockwell Int'l Corp. v. U.S., 147 F.3d 1358, 1362 (Fed. Cir. 1998). Thus, Defendants are not entitled to summary judgment unless they establish by clear and convincing evidence that there is no issue of fact as to whether the patent specifications describe a single electrode embodiment of the claimed inventions.

B. The Specifications Of The '909 Patent, The '536 Patent, And The '281 Patent Describe A Single Electrode Embodiment Of The Claimed Inventions As A Matter Of Law

In support of their motion, defendants rely on the January 1999 reports of Dr. John R. LaCourse and Dr. Robert D. Tucker, who opine that the specifications of the respective patents do not describe any embodiments of claims 40 and 44 of the '909 patent, claim 45 of the '536 patent, and claim 101 of the '281 patent that use only one active electrode. See Declaration of Bradford Schmidt ("Schmidt Decl."), Exhs. N (January 8, 1999 Report of John R. LaCourse

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("LaCourse Decl.") ¶ 26-39) with N (1999 LaCourse Report ¶ 14-29) and Q (July 22, 1998 Declaration of Robert D. Tucker ("Tucker Decl.") ¶ 25-38) with O (1999 Tucker Report ¶ 13-28). .

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("1999 LaCourse Report") F 14-29) and O (January 7, 1999 Report of Robert D. Tucker ("1999 Tucker Report") ¶¶ 13-28).

As a matter of law, these opinions cannot satisfy defendants' burden of proving their written description defense by clear and convincing evidence and as a result, partial summary judgment for ArthroCare is warranted. The opinions of defendants' experts are the same opinions as those presented to, and considered and rejected by, the Court during the proceedings on ArthroCare's motion for a preliminary injunction. At the preliminary injunction stage, defendants provided the Court with extensive briefing, detailed declarations, and testimony from Dr. LaCourse and Dr. Tucker on the question of whether the specifications contained a written description of a single active electrode embodiment. After careful review, the Court determined "that claims 40 and 44 of the '909 patent, claim 45 of the '536 patent, [and] claim 101 of the '281 patent . . . all meet the written description and enablement requirements." See Declaration of Leslie A. Geddes in Support of ArthroCare's Oppositions to Defendants' Motions For Partial Summary Judgment ("Geddes Decl."), Exh. H (December 2, 1998 Memorandum Decision and Order ("December 2 Order") at 24:28-25:2). The Court also found "that the '909 patent describes and enables embodiments with only one electrode." Id. at 25:3-4. Because the '909 specification is incorporated by reference into the specification of the '536 and '281 patents, the Court necessarily found that claim 45 of the '536 patent and claim 101 of the '281 patent meet the written description requirement as to a single electrode embodiment.

At the preliminary injunction stage, ArthroCare, as the moving party, had the "burden of demonstrating that it will likely succeed on all disputed liability issues at trial," including validity issues such as written description. Id. at 4:20-21. The Court's December 2 Order confirms that ArthroCare met that burden as to the written description requirement regarding the single electrode embodiment. Defendants present no new opinions or argument on

Compare Schmidt Decl., Exhs. P (July 21, 1998 Declaration of John R. LaCourse

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this issue in their motion.⁴ Defendants cannot meet their burden of proving lack of written description by clear and convincing evidence by relying on the same opinions and the same arguments that the Court flatly rejected during the preliminary injunction stage of the litigation. Accordingly, ArthroCare, not defendants, is entitled to summary judgment on this issue.

C. At Minimum, There Are Genuine Issues Of Material Fact Sufficient To Defeat Defendants' Motion For Partial Summary Judgment

Even if the Court denies ArthroCare's motion for partial summary judgment, which it should not, ArthroCare raises genuine issues of material fact as to whether the patent specifications provide a written description of the claimed inventions so that a person of ordinary skill would understand that the inventors had possession of a single electrode embodiment.

ArthroCare has set forth ample evidence to defeat defendant's motion. For example, the accompanying declaration of world-renowned electrosurgery expert Dr. Geddes rebuts defendants' contention that the patent specifications do not describe a single electrode embodiment. Dr. Geddes does so by identifying specific portions of the patent specifications that do support a single electrode embodiment. Moreover, Dr. Geddes' opinions are supported by expert Mr. James Doss, who offered his opinions during the preliminary injunction stage, and by the testimony of named co-inventors of the patents-in-suit, Mr. Eggers and Dr. Thapliyal, both of whom explained in deposition that the specifications describe a single electrode embodiment of the claimed inventions. This evidence is more than sufficient to raise a genuine issue of fact.

1. The Specification Of The '909 Patent Describes A Single Electrode Embodiment Of The Claimed Inventions

There is overwhelming evidence that the '909 specification would have demonstrated to one of ordinary skill that ArthroCare was in possession of a single electrode

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In January 1999, defendants served ArthroCare with an expert report from Mr. David J. Parins that addressed the written description issue. Mr. Parins' report cannot raise any genuine issue of material fact on this issue because the relevant portion of that report is virtually identical; word-for-word, to the relevant portion of Dr. LaCourse's January 1999 report. The opinions even include many of the same typographical errors. Furthermore, Mr. Parins, who has only a bachelor of science degree in mechanical engineering, has much less skill in the art than Drs. LaCourse and Tucker, both of whom are university professors and both of whom have Ph.D. degrees.

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embodiment of the claimed inventions. One of ordinary skill would have understood from the '909 specification how to make a single active electrode embodiment of the claimed invention based upon the specification's description of its multi-electrode embodiments.

A person of ordinary skill would understand that the '909 specification describes a single electrode embodiment because many of the disclosed embodiments are essentially collections of single electrodes. The '909 specification teaches that each individual active electrode in a multi-electrode probe operates independently of the other active electrodes. See Geddes Decl. ¶9; Schmidt Decl., Exh. R (August 5, 1998 Declaration of James Doss in Support of ArthroCare's Motion For Preliminary Injunction ("Doss Decl.") ¶ 13). For example, the '909 patent specification teaches that each active electrode in a multi-electrode device is "electrically insulated from all other electrode terminals in the array" and may be connected to its own independently controlled power supply. See Geddes Decl. ¶ 9, Exh. C (the '909 patent at column 6, line 55 to column 7, line 11); Schmidt Decl., Exh. R (Doss Decl. ¶ 13). Further, the '909 specification also explains that each active electrode is independently energizable such that the device can be operated so that "only one" active electrode is energized at a time. See Geddes Decl. ¶ 9, Exh. C (the '909 patent at column 9, lines 25-38); Schmidt Decl., Exh. R (Doss Decl. ¶ 13). The '909 patent specification also explains that the depth of tissue necrosis may be minimized "by energizing only one" active electrode at a time. See Geddes Decl. ¶ 9, Exh. C (the '909 patent at column 12, lines 47-59); Schmidt Decl., Exh. R (Doss Decl. ¶13).

Based on this evidence from the specification, it is the considered opinion of Dr. Geddes that "one of ordinary skill would have understood how to make and use an embodiment of the inventions of claims 40 and 44 having only one active electrode and would have understood that the inventors had possession of such a device." Geddes Decl. ¶9. Dr. Geddes also reviewed the expert reports submitted by Drs. LaCourse and Tucker. Dr. Geddes found that the passages of the '909 specification regarding single electrode devices in the prior art, which were quoted by defendants to support their contention, "do not suggest that . . . single electrode embodiments are not part of the inventions described in the '909 patent." Id. ¶ 10. Indeed, Dr. Geddes found that "[f]ar from suggesting that the '909 specification does not describe or enable

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single electrode embodiments, those passages merely explain that a single large electrode, such as found in prior art devices, was problematic if used in electrically conducting fluids." Id.

Dr. Geddes' appraisal is confirmed by the declaration of Mr. James Doss, rendered during the preliminary injunction stage, that "[o]ne of ordinary skill in the art, in light of the '909 specification, would have understood how to make and use the inventions claimed in claims 40 and 44 with just one active electrode without undue experimentation, and the specification describes the claimed inventions with just one active electrode." See Schmidt Decl., Exh. R. (Doss Decl. ¶ 9).

Dr. Geddes' views are further confirmed by the sworn testimony of the named coinventors of the '909 patent, Mr. Eggers and Dr. Thapliyal. Mr. Eggers testified that "[t]he embodiment having multiple active electrodes is essentially nothing more than a group of independent single active electrodes." See Schmidt Decl., Exh. S (Direct Testimony of Philip E. Eggers in Support of ArthroCare's Motion For Preliminary Injunction, dated September 3, 1998 ("September 3, 1998 Eggers Direct Testimony") at 4:9-10). Dr. Thapliyal concurred with Mr. Eggers, testifying that he does not draw a distinction between multiple and single electrodes because a "Impultiple electrode is a whole bunch of single electrodes." See Schmidt Decl., Exh. T (Transcript of the May 11, 1998 Deposition of Hira V. Thapliyal at 40:23-25).

In addition to the specification text, Figures 13-15 of the '909 patent provide a written description of a single electrode embodiment because they show only one active electrode. See Geddes Decl., Exh. C (the '909 patent at Figs. 13-15). The specification describes each Figure as a detailed view "of a single electrode terminal." Geddes Decl., Exh. C (the '909 patent at column 5, lines 26-31) (emphasis added). In contrast, Figure 12 depicts, and the text describes, an embodiment with multiple active electrodes. See Geddes Decl., Exh. C (the '909 patent at column 5, line 22); Schmidt Decl., Exh. R (Doss Decl. ¶11). Thus, the inventors used the plain language of the specification text, coupled with the drawings, to describe a single electrode embodiment. Further, the swom written testimony of named co-inventor Mr. Eggers confirms that the inventors believed "Figures 13-15 of the '909 patent depict single electrode embodiments." See Schmidt Decl., Exh. S (September 3, 1998 Eggers Direct Testimony at 5:6-

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Despite this Court's finding that Figures 13-15 "do not show a single electrode device." Geddes Decl., Exh. H (December 2 Order at 29:21), the swom testimony of named co-inventor Mr. Eggers and the opinion of Mr. Doss that Figures 13-15 depict a single electrode device raise a

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The application leading to the '536 patent was a divisional of the application leading to the '281 patent. Therefore, the specifications of the '536 and '281 patent are the same.

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The prosecution history of the '281 patent also reveals that the inventors were in possession of the single electrode embodiment when they filed their '281 application on June 7, 1995. The '281 application disclosed a probe having "at least one active electrode." See Schmidt Decl., Exh. U (June 7, 1995 '281 patent application at page 6, line 2). The application also included several independent claims, such as claims 1, 18, and 28, that encompassed single electrode embodiments.

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1 requirement for claims 40 and 44 of the '909 patent, claim 45 of thee '536 patent, and claim 101 2 of the '281 patent and deny defendants' motion. 3 In the alternative, ArthroCare respectfully requests that the Court deny defendants' 4 motion for partial summary judgment of invalidity for failure to satisfy the requirements of 35 5 U.S.C. § 112 because ArthroCare, at minimum, has raised genuine issues of material fact as to the 6 adequacy of the written description. 7 8 Dated: March 18, 1999 WEIL, GOTSHAL & MANGES LLP 9 10 Bradford Schmidt 11 Attorneys for Plaintiff ArthroCare Corporation 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 PL'S OPP'N TO DEFS' MOT. FOR PARTIAL SI OF INVAL

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DECLARATION OF SERVICE 2 I am a citizen of the United States, more than 18 years old, and not a party to this action. My 3 place of employment and business address is 2882 Sand Hill Road, Suite 280, Menlo Park, California. On March 18, 1999, I caused a copy of PLAINTIFF ARTHROCARE'S OPPOSITION TO DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY FOR FAILURE TO SATISFY THE REQUIREMENTS OF 35 U.S.C. 4 5 § 112 to be served on defendants Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. as follows: б BY MAIL I am readily familiar with the business practice at my place of business for collection and processing of correspondence for mailing with the United States Postal Service. Correspondence so collected and processed is deposited with the United States Postal Service that same day in the ordinary course of business. The above document was placed 7 8 in a sealed envelope with first-class postage thereon fully prepaid, and placed for collection and mailing on that date following ordinary business practices. 9 BY FACSIMILE The facsimile machine used to serve the above document 10 on said party or parties produced a record showing that the facsimile transmission was completed successfully. 11 [XXXX] BY OVERNIGHT COURIER SERVICE I am readily familiar with the business practice at my place of business for collection and processing of correspondence for 12 deposit with an overnight delivery service. Correspondence placed for collection and processing 13 is either delivered to a courier or driver authorized by said overnight delivery service to receive documents or deposited by an employee or agent of this firm in a box or other facility regularly 14 maintained by said overnight delivery service that same day in the ordinary course of business. 15 BY HAND DELIVERY I caused said documents to be hand delivered to the parties designated below by delivering copies thereof to a person over the age of eighteen 16 (18) years and not a party to this action. 17 Martin Bern, Esq. George F. Pappas, Esq. Munger, Tolles & Olson LLP Venable, Baetjer, et al. 18 33 New Montgomery Tower, 19th Floor 1201 New York Ave., N.W., Suite 1000 San Francisco, CA 94105-9781 Washington, D.C. 20005 19 (415) 512-4077 (FAX) (202) 962-8300 (FAX) 20 Executed on March 18, 1999, at Menlo Park, California. I declare under penalty 21 of perjury that the foregoing is true and correct. Udi Tellek Judi Tallett 22 23 24 25

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